UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION

This document relates to:

Case No. _____

PASSAMAQUODDY TRIBE–PLEASANT POINT,

Plaintiff,

v.

PURDUE PHARMA L.P., CEPHALON, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., TEVA PHARMACEUTICALS USA, INC., ENDO INTERNATIONAL PLC, ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICALS, INC., INSYS THERAPEUTICS, INC., MALLINCKRODT PLC, MALLINCKRODT LLC, ALLERGAN PLC f/k/a ACTAVIS PLC, ALLERGAN FINANCE LLC f/k/a ACTAVIS, INC. f/k/a WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., ACTAVIS LLC, ACTAVIS PHARMA, INC. f/k/a WATSON PHARMA, INC., AMERISOURCEBERGEN DRUG CORPORATION, CARDINAL HEALTH, INC., McKESSON CORPORATION, OMNICARE DISTRIBUTION CENTER LLC, MASTERS PHARMACEUTICAL, INC., CVS HEALTH CORPORATION, CVS PHARMACY, INC., OMNICARE, INC., WALGREENS BOOTS ALLIANCE, INC., WALGREEN COMPANY, RITE AID CORPORATION, WALMART, INC.,

Defendants.

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

COMPLAINT

DEMAND FOR JURY TRIAL

TABLE OF CONTENTS

COMPLAINT AND DEMAND FOR JURY TRIAL

INTRODUCTION

1. The United States is in the grip of a public health crisis involving opioid misuse and addiction.[1] It is a nationwide epidemic in which millions of people have become addicted to opioids and tens of thousands have died from opioid overdoses.

2. Native Americans and Indian Tribes, including the Plaintiff Passamaquoddy Tribe–Pleasant Point, have been disproportionately impacted by the opioid crisis, suffering much higher rates of misuse, addiction, and overdose deaths related to opioids than other ethnic and socioeconomic groups.[2]

3. The data from the U.S. Centers for Disease Control and Prevention (CDC) on the opioid epidemic are truly shocking. From 1999 to 2016, more than 630,000 people have died from a drug overdose. Around 66% of the more than 63,600 drug overdose deaths in 2016 involved an opioid. On average, 115 Americans die every day from an opioid overdose.[3] Opioids were involved in 42,249 deaths in 2016, and opioid overdose deaths were five times higher in 2016 than 1999.[4]

---

[1] N.D. Volkow, et al., *Opioid Abuse in Chronic Pain–Misconceptions and Mitigation Strategies*, 374 N. Eng. J. Med. 374;13:1253-1263 (March 31, 2016); Maine Attorney General Janet T. Mills, *Maine is losing the war against opioids. Here are 10 steps to turn it around.*, Bangor Daily News (January 7, 2018).

[2] U.S. Senate, Committee on Indian Affairs, Oversight Hearing "Opioids in Indian Country: Beyond the Crisis to Healing the Community," Statements of Senator John Hoeven (R-ND), chairman of the Senate Committee on Indian Affairs, and Michael E. Toedt, MD, Chief Medical Officer, Indian Helath Service (March 14, 2018), available at https://www.indian.senate.gov/sites/default/files/upload/HHS%20IHS%20testimony%20Opioids%20Indian%20Country%20SCIA%203-14-18%20revised.pdf.

[3] CDC, *Opioid overdose, epidemic*, located at https://www.cdc.gov/drugoverdose/epidemic/index.html.

[4] CDC, *Opioid overdose*, *Drug Overdose Death* Data, located at https://www.cdc.gov/drugoverdose/data/statedeaths.html.

4. In the next hour, six Americans will die from opioid overdoses, and two babies will be born addicted to opioids and begin to go through withdrawal. During that same hour, drug manufacturers will earn about $2.7 million from the sale of opioids.

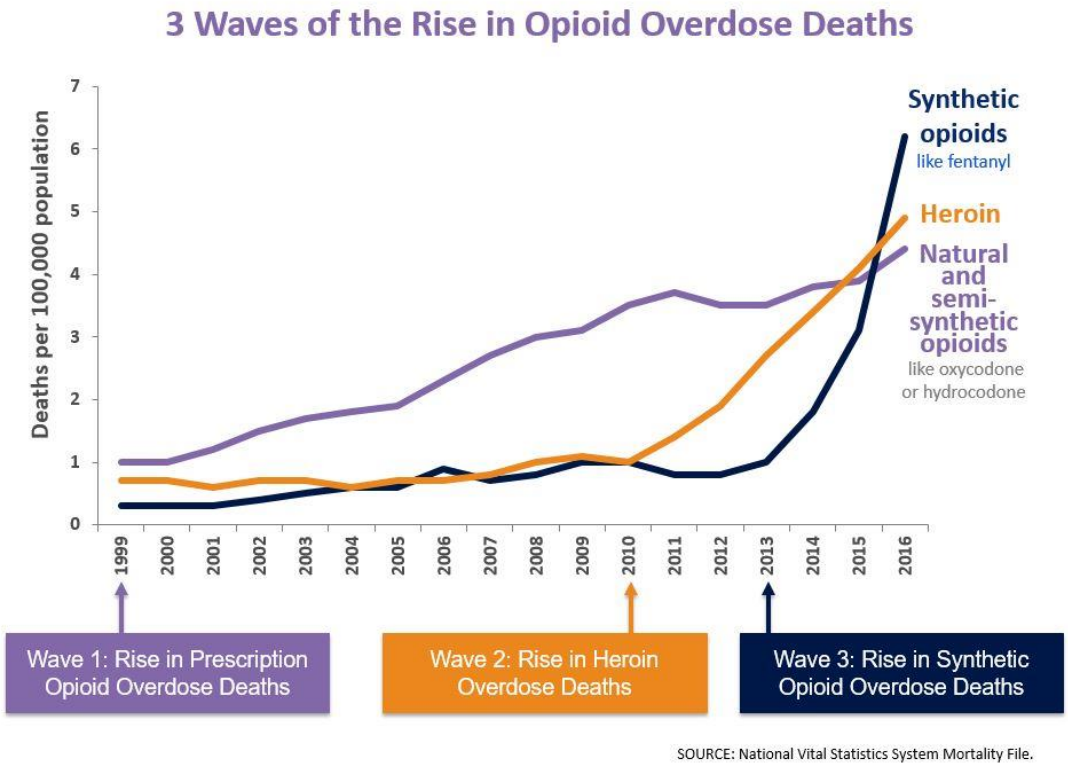
5. Opioids are a class of addictive, narcotic drugs. Used improperly, they are highly dangerous and can lead to addiction and death. Prescription opioids—such as oxycodone (Oxycontin), hydrocodone (Vicodin), morphine, fentanyl, codeine, and others (hereinafter, "opioids")—are used by doctors to treat pain, but they also can be addictive and deadly. Fentanyl is a synthetic opioid which can be prescribed to treat severe pain but is extremely dangerous since even extremely small doses can result in death. Heroin is an illegal opioid which is also addictive and deadly. Most persons with opioid addiction started with prescribed painkillers.[5]

6. Across the country, Americans are addicted to prescription drugs, synthetic opioids, and heroin at levels unprecedented in U.S. history. The opioid epidemic has led to the loss of over 33,000 lives annually, the destruction of countless families and homes, and the incarceration of hundreds of thousands of addicts who have turned to crime in order to support their chemical addictions. The United States comprises less than 5% of the world's population but consumes over 80% of the world's opioid products.

7. Drug overdoses are one of the leading causes of injury and death in the United States and are currently at their highest level ever recorded. Every year since 2011, fatal drug overdoses have outnumbered deaths by firearms and motor vehicle crashes. In 2015,

[5] Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse. Pain management and the opioid epidemic: balancing societal and individual benefits and risks of prescription opioid use. Washington, DC: National Academies of Sciences Engineering Medicine, 2017, located at http://nationalacademies.org/hmd/reports/ 2017/pain-management-and-the-opioid -epidemic.aspx.

approximately 140 people died every day from drug poisoning associated with opioids. The rapid rise in opioid-related overdose deaths is shown in the following CDC chart:[6]



8. The economic damages caused by the opioid crisis are staggering. The CDC estimates that the total economic burden of prescription opioid misuse alone in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.[7]

9. The opioid crisis continues to worsen. The most recent data from CDC shows that opioid overdoses are up another 30 percent from July 2016 to September 2017.[8]

[6] See CDC, *Opioid overdose, epidemic*, located at https://www.cdc.gov/drugoverdose/epidemic/index.html.
[7] National Institute on Drug Abuse, Opioid Overdose Crisis (2018), located at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis.
[8] A. Vivolo-Kantor, et al., *Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses—United States, July 2016-September 2017*, CDC, Morbidity and Mortality Weekly Report, Vol. 67, No. 9, 279-285 (March 9, 2018).

10. This lawsuit targets the two primary causes of the opioid crisis. First, it addresses the deceptive marketing and promotional campaign directed by the opioid manufacturers at the American public, physicians, public health officials, and others. The manufacturers' campaign peddled false information regarding the safety and efficacy of their opioid products which generated a massive increase in the manufacture, sales, distribution, and prescription of opioids.[9] From 1999 to 2014 sales of prescription opioids nearly quadrupled, even though there was no overall change in the amount of pain reported by Americans.[10]

11. The opioid manufacturers' aggressive and deceptive marketing and promotional campaign for their prescription opioid pain relievers began in the mid-1990s. Central to their campaign was a systematic and deceptive effort to minimize the risk of addiction in the use of opioids, particularly for the treatment of chronic non-cancer-related pain.[11] As described by the National Institute for Drug Abuse:

> In the late 1990s, pharmaceutical companies reassured the medical community that patients would not become addicted to prescription opioid pain relievers, and healthcare providers began to prescribe them at greater rates. This subsequently led to widespread diversion and misuse of these medications before it became clear that these medications could indeed be highly addictive. Opioid overdose rates began to increase. In 2015, more than 33,000 Americans died as a result of an opioid overdose, including prescription opioids, heroin, and illicitly manufactured fentanyl, a powerful synthetic opioid. That same year, an estimated 2 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers, and 591,000 suffered from a heroin use disorder (not mutually exclusive).[12]

[9] CDC, *Opioid overdose*, located at https://www.cdc.gov/drugoverdose; R. Rudd, et al., *Increases in Drug and Opioid Overdose Deaths—United States, 2000-2014*, CDC, Morbidity and Mortality Weekly Report, 64 (50 & 51), 1378-1382 (Jan. 1, 2016).
[10] CDC, *Vital Signs: Overdoses of Prescription Opioid Pain Relievers United States, 1999-2008*, Morbidity and Mortality Weekly Report 2011; 60(43);1487-1492.
[11] A. Van Zee, *The Promotion and Marketing of Oxycontin: Commercial Triumph, Public Health Tragedy*, Am. J. Pub. Health; 99(2), 221-227 (February 2009).
[12] National Institute on Drug Abuse, *Opioid Overdose Crisis* (2018), located at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis.

12. The opioid manufacturers aggressively pressed deceptive and fraudulent campaign tactics in order to influence the medical profession to prescribe more opioids, and particularly for use of opioids in the non-malignant pain market.[13] Defendant Purdue Pharma, for example, among other tactics, spent millions of dollars on lobbying, held all-expenses paid pain management and speaker-training conferences for medical professionals (physicians, nurses, pharmacists), targeted physicians who were high-volume opioid prescribers in order to influence them to increase opioid prescriptions, increased their opioid-related sales force and drug representatives and instituted a lucrative bonus system linked to increased sales of opioids, and distributed branded promotional items (e.g., OxyContin fishing hats) to medical professionals.[14]

13. As part of their aggressive over-promotion and marketing of these highly addictive, dangerous opioid products the Manufacturer Defendants also misrepresented to the federal government that the risk of opioid addiction and dependence was rare. In violation of federal law, the Manufacturer Defendants also misled the government and the public about various aspects of these opioid drugs, promoting opioids as miracle pills that could relieve pain without any real risk of addiction. Building upon those falsehoods, the Manufacturer Defendants, as defined below, launched and funded aggressive campaigns to convince doctors, and the general public, that opioids could safely be used as a daily treatment for chronic pain.

14. The misinformation campaign worked. Across the country, doctors and dentists began prescribing highly addictive opioids for ailments ranging from neck pain to headaches to tooth aches. At the same time, in response to the aggressive marketing campaigns, public demand for opioids soared. That demand, in turn, created a cottage industry of "pill mills," where

[13] A. Van Zee, *The Promotion and Marketing of Oxycontin: Commercial Triumph, Public Health Tragedy*, Am. J. Pub. Health; 99(2), 221-227 (February 2009).

[14] *Id.*

unscrupulous doctors handed out opioid prescriptions for even the most minor (claimed) ailments, without any consideration of the drugs' highly addictive properties.

15. Predictably, many of these highly addictive opioids ultimately found their way into the black market. There, they were sold to recreational users, to former pain patients suffering from addiction, and to children and teenagers, who in turn became addicted. When addicted people became unable to afford prescription drugs—or when they reached a point where prescription opioids no longer satiated their withdrawal symptoms—many of them turned to an even deadlier opioid: heroin.

16. Second, this action also focuses upon the opioid distributors who, along with the manufacturers and national retail pharmacies, deliberately evaded and ignored federal and state laws and regulations controlling and restricting opioid distribution. The combined efforts of the manufacturers, distributors, and retail pharmacies resulted in misuse, abuse, over-prescription, and diversion of opioids leading to a nationwide epidemic of unprecedented proportions.

17. Aware that opioids can have devastating effects if diverted to the black market, the U.S. Congress in the 1970s enacted laws and regulations which created a system requiring any drug manufacturer, distributor, or retailer to: (1) report suspicious orders of prescription opioids to the Drug Enforcement Administration ("DEA"); and (2) perform required due diligence prior to filling any suspicious orders. *See* Controlled Substances Act (CSA), 21 U.S.C. § 823(b)(1); 21 C.F.R. § 1301.74(b).

18. States, including the State of Maine, have enacted laws and regulations which incorporate virtually all the federal CSA and its regulations pertaining to opioids. See Maine Pharmacy Act, 32 MRSA §13701 *et seq*.

19. Despite these laws and regulations, however, the defendants' have deliberately evaded federal and state laws and regulations specifically enacted to control opioid drugs and to prevent their misuse, and diversion to illegal markets. If these corporate actors had only followed these federal and state laws law, the torrential flow of prescription opioids into American homes, schools, towns and cities would have been prevented and opioid misuse and diversion could have been dramatically reduced or eliminated.

20. Instead, manufacturers, distributors, and retailers chose not to follow federal and state law, and, when presented with absurdly large opioid orders manufacturers, distributors, and retailers chose to look the other way.

21. Defendants reaped staggering profits because of their corporate malfeasance. For example, in the mid-1990s, defendant Purdue Pharma's annual sales of OxyContin, were around $1 billion. However, by 2015 sales increased to nearly $10 billion, and, by 2020, annual sales are expected to reach $18 billion.[15]

22. The economic damages caused by the opioid crisis are staggering. The CDC estimates that the total economic burden of prescription opioid misuse alone in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.[16]

23. The opioid epidemic has been unsparing, and undiscriminating, in the victims it has claimed. Opioids—profligately sold to treat virtually any ailment—have destroyed the lives of countless men and women who had the misfortune of suffering from back pain, arthritis, workplace injuries and a countless array of other relatively minor and term-limited painful conditions.

[15] Centerwatch.com, *Report: Opioid pain sales to hit $18.4B in the U.S. by 2020* (July 17, 2017), available at https://www.centerwatch.com/news-online/2017/07/17/report-opioid-pain-sales-hit-18-4b-u-s-2020/.
[16] National Institute on Drug Abuse, Opioid Overdose Crisis (2018), located at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis.

Opioids have devastated families whose teenaged sons and daughters were killed by accidental overdoses. America's raging opioid epidemic has turbocharged the heroin trade, as people addicted to prescription opioids often end up turning to highly potent street drugs.

24. In prioritizing profit over legal duty, the prescription drug industry wreaked havoc on the lives of countless Americans, including Native Americans and Indian Tribes. Along the way, the industry drained the coffers of local governmental entities across the country, including those of Indian Tribes like the Passamaquoddy Tribe–Pleasant Point, forcing them to shoulder increased costs associated with the opioid epidemic.

25. By this action, the Plaintiff Passamaquoddy Tribe–Pleasant Point seeks to recover all its damages which defendants' actions directly and foreseeably caused, including its costs related to (a) providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (b) costs for providing treatment, detox, counseling, and rehabilitation services; (c) costs for providing treatment of infants born with opioid-related medical conditions; (d) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; and (e) costs associated with social services, law enforcement, and public safety relating to the opioid epidemic, as well as other damages and relief.

PARTIES

I. Plaintiff[SA1]

26. Plaintiff, the Passamaquoddy Tribe–Pleasant Point (hereinafter "Plaintiff", "Pleasant Point," or "Tribe"), is a federally recognized Indian tribal government and a subdivision of the Passamaquoddy Tribe with governmental authority over the Passamaquoddy Pleasant Point Reservation also known as "Motahkomikuk" (hereinafter "Reservation"). The Tribe maintains a

principal place of business located at 15 Elders Way #201, Pleasant Point, Maine 04657.[17] The Passamaquoddy Tribe has inherent government authority to exercise on behalf of itself and its members.

27. Plaintiff has standing to bring the instant claims including, *inter alia*, claims for violations under the Racketeer Influenced and Corrupt Organizations Act ("RICO Act"), because Plaintiff qualifies as a "person" within the meaning of the RICO Act. *See* 18 U.S.C. § 1961(3); 18 U.S.C. § 1964(c).

II. Defendants

A. Manufacturer Defendants

28. The Manufacturer Defendants defined below have manufactured, packaged, labeled, advertised, promoted, marketed, sold, and distributed prescription opioid products on a nationwide basis, including in the State of Maine. The Manufacturer Defendants implemented a massive and fraudulent marketing and promotional campaign which mispresented the safety and efficacy of their opioid products which deceived the medical profession and the public and triggered the present opioid crisis and reaped billions of dollars in profits for the Manufacturer Defendants. The Manufacturer Defendants further failed to fulfill their legal duties under federal and state law to, among other things, establish and maintain effective controls against diversion of prescription opioids into other than legitimate medical or industrial channels. The Manufacturer Defendants are defined as "wholesale distributors" under applicable federal and state laws and regulations and were an integral part of the prescription opioid supply chain.

29. Defendant Purdue Pharma L.P. is a Delaware limited partnership with its headquarters and principal place of business located in Stamford, Connecticut. The company

[17] Indian Entities Recognized and Eligible to Receive Services from the United States Bureau of Indian Affairs, 81 Fed. Reg. 19, 5019-5025 (January 29, 2016).

maintains four operational branches: Purdue Pharma L.P., the Purdue Frederick Company, Purdue Pharmaceutical Products L.P., and Purdue Products L.P. (collectively referred to herein as "Purdue").

30. Purdue manufactures, promotes, distributes and sells prescription opioids such as OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER. These opioids are manufactured in the United States and promoted, distributed, and sold across the U.S.—including in the State of Maine and the Passamaquoddy Tribe–Pleasant Point. OxyContin is Purdue's best-selling opioid. Since 2009, Purdue's annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from its 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs, otherwise known as painkillers.

31. Defendant Cephalon, Inc. ("Cephalon, Inc.") is a Delaware corporation with its headquarters and principal place of business located in Frazer, Pennsylvania. In October 2011, Cephalon, Inc. was acquired by Defendant Teva Pharmaceutical Industries Ltd.

32. Defendant Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is incorporated under the laws of the State of Israel with its headquarters and principal place of business in Petah Tikva, Israel. Since Teva Ltd. acquired Cephalon, Inc., its U.S. sales and marketing activities have been conducted by Defendant Teva Pharmaceuticals USA, Inc.

33. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a wholly-owned operating subsidiary of Teva Ltd. Teva USA's headquarters and principal place of business are in North Wales, Pennsylvania. Teva Pharmaceutical Industries Ltd. and Teva Pharmaceuticals USA, Inc. are collectively referred to herein as "Teva." Cephalon, Inc., Teva Ltd. and Teva USA are collectively referred to herein as "Cephalon."

34. Cephalon manufactures, promotes, distributes and sells prescription opioids such as Actiq and Fentora. These opioids are manufactured in the United States and promoted, distributed, and sold across the U.S.—including in the State of Maine and the Passamaquoddy Tribe–Pleasant Point. Actiq and Fentora have been approved by the United States Food and Drug Administration ("FDA") only for the "management of breakthrough cancer pain in patients 16 years of age and older who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain."

35. Defendant Endo International PLC ("Endo PLC") is a public limited company organized under the laws of the State of Ireland with its headquarters and principal place of business in Dublin, Ireland.

36. Defendant Endo Health Solutions, Inc. ("Endo Health") is a Delaware corporation with its headquarters and principal place of business in Malvern, Pennsylvania. Endo Health Solutions, Inc. is a wholly-owned subsidiary of Endo International PLC.

37. Defendant Endo Pharmaceuticals Inc. ("Endo Inc.") (Endo International PLC, Endo Health Solutions, Inc. and Endo Inc. are collectively referred to herein as "Endo") is a Delaware corporation with its headquarters and principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals Inc. is a wholly-owned subsidiary of Endo Health and an indirectly wholly-owned subsidiary of Endo International PLC.

38. Endo manufactures, promotes, distributes and sells prescription opioids such as Opana/Opana ER, Percodan, Percocet, and Zydone. These opioids are manufactured in the United States and promoted, distributed, and sold across the U.S.—including in the State of Maine and the Passamaquoddy Tribe–Pleasant Point. In 2012, opioids made up roughly $403 million of Endo's $3 billion total revenues. Opana ER yielded $1.15 billion in revenue from 2010 and 2013,

and the drug accounted for 10% of Endo's total revenue in 2012. Additionally, Endo manufactures, promotes, distributes and sells generic opioids such as oxycodone, oxymorphone, hydromorphone, and hydrocodone products. These opioids are manufactured in the United States and promoted, distributed, and sold across the U.S.—including in the State of Maine and the Passamaquoddy Tribe–Pleasant Point reservation—by and through Endo and its subsidiary, Qualitest Pharmaceuticals, Inc.

39. Defendant Janssen Pharmaceuticals, Inc. ("Janssen"), formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica, is a New Jersey corporation with its headquarters and principal place of business in Titusville, New Jersey and Raritan, New Jersey. Janssen is a wholly-owned subsidiary of Johnson & Johnson, a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

40. Janssen manufactures, promotes, distributes and sells prescription opioids such as Duragesic, Nucynta and Nucynta ER. These opioids are manufactured in the United States and promoted, distributed, and sold across the U.S.—including in the State of Maine and the Passamaquoddy Tribe–Pleasant Point reservation. Prior to 2009, Duragesic accounted for, at least, $1 billion in annual sales. Prior to January 2015, Janssen manufactured, promoted, distributed and sold the prescription opioids Nucynta and Nucynta ER. In 2014, Nucynta and Nucynta ER collectively accounted for $172 million in sales.

41. Defendant Insys Therapeutics, Inc. ("Insys") is a Delaware corporation with its headquarters and principal place of business in Chandler, Arizona. Insys manufactures, promotes, distributes and sells prescription opioids such as Subsys. These opioids are manufactured in the United States and promoted, distributed, and sold across the U.S.—including in the State of Maine and the Passamaquoddy Tribe–Pleasant Point reservation.

42. Defendant Mallinckrodt PLC ("Mallinckrodt PLC") is a public limited company organized under the law of the State of Ireland with its headquarters and principal place of business in Staines-Upon-Thames, Surrey, United Kingdom.

43. Defendant Mallinckrodt LLC ("Mallinckrodt LLC") (Mallinckrodt PLC and Mallinckrodt LLC are collectively referred to herein as "Mallinckrodt") is a Delaware corporation with its headquarters and principal place of business in Hazelwood, Missouri.

44. Mallinckrodt manufactures, promotes, distributes and sells prescription opioids such as Exalgo, Roxicodone, Xartemis XR, Methadone, Morphine sulfate extended release, and fentanyl, among other generic opioids. These opioids are manufactured in the United States and promoted, distributed, and sold across the U.S.—including in the State of Maine and the Passamaquoddy Tribe–Pleasant Point reservation. Mallinckrodt is the largest U.S. supplier of prescription opioid pain medications and is among the top ten generic pharmaceutical manufacturers of prescription opioid pain medications in the United States, based on prescriptions.

45. Defendant Allergan PLC, formerly known as Actavis PLC, is a public limited company incorporated under the laws of the State of Ireland with its headquarters and principal place of business in Dublin, Ireland.

46. Defendant Allergan Finance LLC, formerly known as Actavis, Inc., formerly known as Watson Pharmaceuticals, Inc., is a Delaware limited liability company with its headquarters and principal place of business in Parsippany, New Jersey.

47. Defendant Watson Pharmaceuticals, Inc., now known as Actavis, Inc., is a Delaware limited liability company with its headquarters and principal place of business in Parsippany, New Jersey.

48. Defendant Watson Laboratories, Inc. is a Nevada corporation with its headquarters and principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC.

49. Defendant Actavis LLC is a Delaware limited liability company with its headquarters and principal place of business in Parsippany, New Jersey.

50. Defendant Actavis Pharma, Inc., formerly known as Watson Pharma, Inc., is a Delaware corporation with its headquarters and principal place of business in New Jersey.

51. Allergan Finance LLC, Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. are owned by Allergan PLC, which operates subsidiary companies to market and sell pharmaceutical drugs in the U.S. Upon information and belief, Allergan PLC exercises control over each subsidiary company, including marketing and sales efforts. Upon information and belief, profits from the sale of Allergan PLC products ultimately inure to Allergan PLC's benefit.

52. Allergan PLC, Actavis PLC, Allergan Finance LLC, Actavis, Inc., Watson Laboratories, Inc., Actavis LLC, Actavis Pharma, Inc., and Watson Pharma, Inc. are collectively referred to herein as "Actavis."

53. Actavis manufactures, promotes, distributes and sells prescription opioids such as the brand-name drugs Kadian and Norco, a generic version of Kadian, and generic versions of Duragesic and Opana. These opioids are manufactured in the United States and promoted, distributed, and sold across the U.S.—including in the State of Maine and the Passamaquoddy Tribe–Pleasant Point reservation. On December 30, 2008, Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. and, subsequently, began marketing Kadian in 2009.

54. The Manufacturer Defendants listed above are all engaged in the manufacturing of opioids. The Manufacturer Defendants listed above are collectively referred to herein as the "Manufacturer Defendants."

55. The failure of all Manufacturer Defendants to effectively monitor and report suspicious orders of prescription opioids, their aggressive misinformation campaign aimed at increasing public consumption of highly addictive opioids, their failure to forthrightly provide accurate information to FDA, their failure to adhere to FDA regulations regarding misbranding, their failure to implement measures to prevent the filling of suspicious orders, and their perverse utilization of so-called "patient advocacy" groups to evade FDA regulations concerning consumer drug-marketing greatly contributed to a vast increase in opioid overuse and addiction. Manufacturer Defendants' conduct thus directly caused a public-health and law-enforcement crisis across this country, including in the Passamaquoddy Tribe–Pleasant Point reservation.

B. Distributor Defendants

56. The Distributor Defendants defined below have distributed, supplied, sold, and placed into the stream of commerce, the prescription opioid products without fulfilling their legal duties under federal and state law to, among other things, establish and maintain effective controls against diversion of prescription opioids into other than legitimate medical or industrial channels. The Distributor Defendants are defined as "wholesale distributors" under applicable federal and state laws and regulations. The Distributor Defendants were an integral part of the prescription opioid supply chain.

57. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a Delaware corporation with its headquarters and principal place of business located in Chesterbrook, Pennsylvania.

58. Defendant Cardinal Health, Inc. ("Cardinal Health") is a Delaware corporation with its headquarters and principal place of business located in Dublin, Ohio.

59. Defendant McKesson Corporation ("McKesson") is a Delaware corporation with its headquarters and principal place of business located in San Francisco, California.

60. Defendant Omnicare Distribution Center LLC, ("Omnicare") is a Delaware limited liability company with its headquarters and principal place of business in Cincinnati, Ohio.

61. Defendant, Masters Pharmaceutical, Inc., ("Masters") is an Ohio limited liability company with its headquarters principal place of business in Cincinnati, Ohio.

62. The distributor defendants listed above are all engaged in the wholesale distribution of opioids. The distributor defendants listed above are collectively referred to herein as the "Distributor Defendants."

63. The failure of all Distributor Defendants to effectively monitor and report suspicious orders of prescription opioids and to implement measures to prevent the filling of improper prescriptions greatly contributed to the vast increase in opioid overuse and addiction. Distributor Defendants' conduct thus directly caused a public-health and law-enforcement crisis across this country, including in the Passamaquoddy Tribe–Pleasant Point reservation.

C. Retailer Defendants

64. The Retail Pharmacy Defendants (also "Retailer Defendants") defined below have distributed, supplied, filled prescriptions, sold, and placed into the stream of commerce, the prescription opioid products without fulfilling their legal duties under federal and state law to, among other things, establish and maintain effective controls against diversion of prescription opioids into other than legitimate medical or industrial channels. The Retail Pharmacy Defendants were an integral part of the prescription opioid supply chain.

65. Defendant CVS Health Corporation ("CVS Health") is a Delaware corporation with its headquarters and principal place of business in Woonsocket, Rhode Island. CVS has 27 retail pharmacies in Maine.

66. Defendant CVS Pharmacy, Inc. ("CVS Pharmacy") is a wholly-owned operating subsidiary of CVS Health, incorporated in the State of Rhode Island with its headquarters and principal place of business in Woonsocket, Rhode Island.

67. Defendant Omnicare, Inc. ("Omnicare, Inc.") is a wholly-owned operating subsidiary of CVS Health, incorporated in the State of Delaware with its headquarters and principal place of business in Woonsocket, Rhode Island.

68. Defendant CVS Health, Defendant CVS Pharmacy and Defendant Omnicare, Inc. are collectively referred to as "CVS".

69. Defendant Walgreens Boots Alliance, Inc. ("Walgreens Boots Alliance") is a Delaware corporation with its headquarters and principal place of business located in Deerfield, Illinois. Walgreens has 14 stores in Maine.

70. Defendant Walgreen Company ("Walgreen Co.") is a wholly-owned operating subsidiary of Walgreens Boots Alliance, incorporated in the State of Illinois with its headquarters and principal place of business in Deerfield, Illinois.

71. Defendant Walgreens Boots Alliance and Defendant Walgreen Co. are collectively referred to as "Walgreens".

72. Defendant Rite Aid Corporation ("Rite Aid Corp.") is a Delaware corporation with its headquarters and principal place of business located in Camp Hill, Pennsylvania. Rite Aid has 79 stores in Maine, including in Calais, Maine.

73. Defendant Wal-Mart Inc., formerly known as Wal-Mart Stores, Inc. ("Wal-Mart" or "Walmart"), is a Delaware Corporation with its principal place of business in Arkansas. At all times relevant to this Complaint, Wal-Mart distributed prescription opioids throughout the United States, including in the State of Maine. Wal-Mart has 20 stores in Maine, including in Calais, Maine.

74. The retailer defendants listed above are all engaged in the business of retail selling of opioids. The retailer defendants are collectively referred to herein as the "Retailer Defendants."

75. The failure of all Retailer Defendants to effectively monitor and report suspicious orders of prescription opioids and to implement measures to prevent filling of improper prescriptions greatly contributed to the vast increase in opioid overuse and addiction.

76. Additionally, Retailer Defendants foisted a perverse incentive system on their employees that prevented their pharmacists from meeting their obligations under federal and Maine law. In so doing, Retailer Defendants greatly contributed to the vast increase in opioid overuse and addiction.

77. Retailer Defendants' conduct thus directly caused a public-health and law-enforcement crisis across this country, including in the Passamaquoddy Tribe–Pleasant Point.

78. The Manufacturer Defendants, Distributor Defendants and Retail Pharmacy Defendants are also collectively referred to herein as the "Defendants."

JURISDICTION AND VENUE

79. This Court has subject matter jurisdiction over this action in accordance with 28 U.S.C. § 1332(a). Complete diversity exists between Plaintiff (a citizen of the State of Maine) and Defendants (citizens of states other than Maine). The amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

80. This Court also has subject matter jurisdiction under 28 U.S.C. § 1331 based upon the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq*. ("RICO Act"). This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367, as the state law claims are so related to Plaintiff's federal law claims that the claims form part of the same case or controversy.

81. Venue is proper within this District pursuant to Case Management Order No. 1 regarding direct filing of actions in In re: National Prescription Opiate Litigation, MDL No. 2804 ("MDL 2804"), for purposes of coordinated and consolidated pretrial proceedings (Hon. Dan A. Polster). See In re: National Prescription Opiate Litigation, Case 1:17-md-02804-DAP, Doc # 232, CMO1 (6)(a) (April 11, 2018).

82. Venue is proper within the District of Maine pursuant to 28 U.S.C. § 1391, as this District is a judicial district where Defendants are subject to personal jurisdiction in accordance with 28 U.S.C. §§ 1391(a) and (c), as well as 14 M.R.S.A. § 704-A, the Maine Long-Arm statute.

83. This Court has personal jurisdiction over Defendants as they conduct business in Maine and Ohio, purposefully direct or directed their actions toward Maine and Ohio, consented to be sued in Maine and Ohio by registering an agent for service of process, consensually submitted to the jurisdiction of Maine and Ohio when obtaining a manufacturer or distributor license, and have the requisite minimum contacts with Maine and Ohio necessary to constitutionally permit this Court to exercise jurisdiction.

84. Defendants are non-domiciliaries of the states of Maine or Ohio and regularly engage in business within the states of Maine and Ohio. Defendants have committed tortious acts outside and within the states of Maine and Ohio that have caused injury within Maine to the Plaintiff. Defendants expect or should reasonably have expected those acts to have consequences

in the State of Maine. Defendants, moreover, solicited business within the State of Maine, engaged in persistent courses of conduct in the State of Maine, and derived substantial revenue from goods used and services rendered in the State of Maine through interstate commerce.

85. Defendants are regularly engaged in the business of manufacturing, distributing and dispensing prescription opioids, either directly or indirectly through third-party related entities, in the states of Maine and Ohio, as well as in the Passamaquoddy Tribe–Pleasant Point reservation lands. Defendants' activities in the Passamaquoddy Tribe–Pleasant Point reservation lands in connection with the manufacture, distribution and dispensation of prescription opioids was, and is, continuous and systematic, and gave rise to the causes of action alleged herein.

FACTUAL ALLEGATIONS

I. Overview of the Opioid Crisis

86. Addiction is a devastating disease. It alters the brain's neurochemistry and significantly impairs cognitive, behavioral, and emotional functioning. In those addicted it results in compulsive, self-destructive behaviors, damage to interpersonal and familial relationships, burdensome medical and societal costs, and criminal activity. Often, addiction results in permanent disability or premature death.[18]

[18] See American Society of Addiction Medicine, Public Policy Statement: Definition of Addiction (August 15, 2011), available at https://www.asam.org/resources/definition-of-addiction; NIH, National Institute of Drug Abuse, *Drugs, Brains, and Behavior: The Science of Addiction* (July 2014), available at https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/drug-abuse-addiction.

87. Opioids are a class of drugs primarily derived from opium which is obtained from the poppy plant.[19] All opioids can be highly addictive.[20] Opioids are among the world's oldest drugs and have been used for well over 5,000 years.[21] Since ancient times, opium has been used for medical, religious, and illicit purposes, and its highly addictive properties have been well known.[22]

88. Natural opioid analgesics such as morphine and codeine are derived from opium. Morphine is processed chemically to produce heroin.[23]

89. Semi-synthetic opioid analgesics include drugs such as oxycodone, hydrocodone, hydromorphone, and oxymorphone. They are "semi-synthetic" opioids because their production begins with the raw material for opium but laboratory and chemical processes are then employed to produce a new compound.[24]

[19]Traditionally, the term "opiate" was used in pharmacology to refer drugs derived from the opium. Opiates are alkaloid compounds naturally found in the opium poppy plant, Papaver somniferum. These opiate alkaloid compounds include heroin, morphine, codeine, and thebaine; each has a high potential for addiction. "Opioid" is a more modern term used to refer to all substances, both natural and synthetic, that bind to opioid receptors in the human brain. Opioid is, therefore, a broader term than opiate, and it also encompasses synthetic opiates (e.g., fentanyl, meperidine, and methadone) and semi-synthetic opiates (e.g., hydrocodone, hydromorphone, oxycodone, and oxymorphone).

[20] NIH, National Institute of Drug Abuse, *Drug Facts: Prescription Opioids* (January 2018), available at https://www.drugabuse.gov/publications/drugfacts/prescription-opioids.

[21] Manglik, A., et al., Nature; *Crystal structure of the μ-opioid receptor bound to a morphinan antagonist*, 485(7398): 321–326 (December 16, 2012); Berger, A., et al., *How to Design and Opioid Drug That Causes Reduced Tolerance and Dependence*, Ann. Neurology, 67(5):559-569 (May 2010).

[22] Freemantle, M., Chemical and Engineering News, *The Top Pharmaceuticals That Changed The World, Morphine*, Vol. 83, Issue 25 (6/20/05); Brownstein, M., Proc. Natl. Acad. Sci. USA, *A brief history of opiates, opioid peptides, and opioid receptors*, Vol. 90, pp. 5391-5393 (June 1993).

[23] Offermanns, Stefan, *Encyclopedia of Molecular Pharmacology*, ***1*** *(2 ed.), p. 903,* Springer Science & Business Media *(2008)*

[24] Enno Frye, *Opioids in Medicine: A Comprehensive Review of the Mode and Action of the Use of Analgesics in Different Pain States*, Springer Science & Business Media, p. 85 (2008).

90. Synthetic opioid analgesics include drugs such as fentanyl and methadone.[25] These opioids are "synthetic" because they are synthesized from laboratory chemicals and are not derived from natural opium or the poppy plant.

91. All opioids are chemically related and interact with opioid receptors on nerve cells in the body and brain. Prescription opioid pain relievers are generally safe when taken for a short time but because they produce euphoria in addition to pain relief, they can be misused. Regular use—even as prescribed by a doctor—can lead to dependence and, when misused, opioid pain relievers can lead to addiction, overdose incidents, and deaths.[26]

92. For over a century, pharmaceutical companies have attempted to change the chemical composition of naturally occurring opioids to create a drug that targets pain without creating addiction. These efforts, however, have consistently resulted in unequivocal failure.

93. Heroin, for example, was invented in the nineteenth century and was derived from opium in an effort to find a non-addictive form of morphine. Now widely known as a highly addictive street drug, heroin was initially marketed as an addiction-proof pain medication. Indeed, the word "heroin" is in fact a brand name invented by the pharmaceutical company Bayer.

94. The similarities between the marketing of heroin and the marketing of prescription opioids are strikingly similar. Much like the opioids at issue in this complaint, a perverse parade of salesman and traveling promoters once claimed that heroin was non-addictive and safe in virtually every clinical context. Of course, those claims turned out to be false. And the

[25] U.S. DEA, *Drugs of Abuse*, p. 38 (2017), available at https://www.dea.gov/pr/multimedia-library/publications/drug_of_abuse.pdf; U.S. DEA, *Fentanyl FAQs*, available at https://www.dea.gov/druginfo/fentanyl-faq.shtml.

[26] NIH, National Institute of Drug Abuse, *Drugs, Brains, and Behavior: The Science of Addiction* (July 2014), available at https://www.drugabuse.gov/publications/drugs-brains-behavior-science-addiction/drug-abuse-addiction.

pharmaceutical industry, having fattened its wallets with proceeds from heroin, left a generation of addicts in its wake.

95. For much of the twentieth century (and partially because of the catastrophic failure of purportedly "addiction-proof" heroin) long-term opioid use was primarily reserved for palliative care for cancer patients in severe pain, or for the terminally ill. Doctors and medical professionals understood the serious risks associated with any opioid use exceeding mere days. Those risks, including addiction, overdose, and death, significantly outweighed the benefits of the drug's pain-relieving effects.

96. Accordingly, prior to the 1990's, doctors used opioid pain relievers sparingly, and only in the short term, for cases of severe injury or illness, or during surgery.[27] Doctors' reluctance to use opioids for an extended period of time, despite their short-term effectiveness for pain, sprang from the legitimate fear of causing addiction.[28]

97. However, beginning in the late 20th century, and continuing through today, the pharmaceutical industry acted to dramatically expand the marketplace for opioids. As set forth below, pharmaceutical actors facilitated this expansion in two ways. First, pharmaceutical manufacturers engaged in a misinformation campaign which altered public perception of opioids, and deceived doctors, federal regulators, and the public about their addictive qualities. Second, opioid manufacturers, wholesalers, and retailers flouted their federally imposed requirements to report suspicious opioid orders to the DEA. That, in turn, facilitated an explosion in the illegitimate marketplace for prescription opioids.

98. Because opioids and other drugs are highly addictive they are subject to illicit use and criminal activity. Opioid alkaloids and related pharmaceuticals represent one of the largest

[27] Meldrum ML, *Progress in Pain Research and Management*, Vol. 25 Seattle, WA: IASP Press; 2003.
[28] *Id*.

components of the illicit drug market world-wide, generating revenue of approximately $70 billion in 2009, much of which supports crime, wars, and terrorism.[29]

99. As a result, governments worldwide have enacted laws to control and restrict the abuse of opioids to protect the public health. In the United States, Congress enacted laws which strictly regulate the marketplace for medical opioids. Pursuant to the Controlled Substances Act of 1970 ("CSA"), the federal Drug Enforcement Agency ("DEA") annually caps the aggregate number of opioids that could be produced in the United States. 21 U.S.C. § 826(a); 28 C.F.R. § 0.100. Under the CSA, moreover, opioids can be sold only through a controlled, highly regulated distribution network that requires manufacturers, wholesale distributors, and retailers to act as substance-abuse watchdogs, and report any suspicious orders of opioids to the DEA. 21 C.F.R. § 1301.74(b).

100. Each of the states in the United States has also enacted laws and regulations to regulate opioids. In Maine, opioids are strictly regulated under state law by the Maine Pharmacy Act, 32 M.R.S.A. § 13701, et seq., and the regulations of the Maine Board of Pharmacy, 02-392 CMR Pt. 1 et seq., which incorporate various federal laws, including the Federal Food, Drug and Cosmetics Act (FDCA), 21 U.S.C. §301 et seq., and the Controlled Substances Act (CSA), 21 U.S.C. §801 et seq. and its accompanying regulations. See Maine Board of Pharmacy, 02-392 CMR Pt. 5, Ch. 29, §1 (1, 2, 6).

II. The Opioid Epidemic's Devastating Effects in the United States

101. Opioid addiction in the United States has skyrocketed as a result of: (1) the Manufacturer Defendants' misinformation campaigns, and (2) Defendants' failure to abide by their obligations under the CSA and Maine state law. Defendants' actions created an opioid ecosystem

[29] Manglik, A., et al., Nature; *Crystal structure of the μ-opioid receptor bound to a morphinan antagonist*, 485(7398): 321–326 (December 16, 2012).

in which prescriptions for highly addictive drugs could be easily obtained, and easily filled. Overprescribing, in turn, drove opioid-related addiction, overdose, and infections, and it sustained nonmedical use of prescription opioids.[30]

102. All Defendants were aware of bad-faith prescribing practices. Yet, far from doing anything to stop the practice of overprescribing, Defendants acted to fuel it. Defendants are thus responsible for the opioid epidemic that, as set forth below, has devastated America and imposed severe burdens on the Passamaquoddy Tribe–Pleasant Point.

A. Deaths from Prescription Opioid Overdoses

103. In 2015, it is estimated that 91.8 million people—more than one-third of the population of civilian, noninstitutionalized U.S. adults—used prescription opioids. For many of those people, opioid use will prove fatal.[31]

104. Since 1999, two hundred thousand Americans have died because of overdoses from OxyContin and other prescription opioids.[32] Overdose deaths involving prescription opioids were five times higher in 2016 than 1999. The most common drugs involved in prescription opioid overdose deaths include: Methadone, Oxycodone (such as OxyContin®), and Hydrocodone (such as Vicodin®).[33]

105. Overdose rates from prescription opioids were higher among American Indian or Alaskan Natives, compared to non-Hispanic blacks and Hispanics.[34]

---

[30] L. Manchikanti et al., *Opioid Epidemic in the United States*. 15 PAIN PHYSICIAN ES9–38 (supplemental material) (2012); AM Arria & WM Compton, *Complexities In Understanding and Addressing the Serious Public Health Issues Related to the Nonmedical Use of Prescription Drugs*, 65 ADDICT BEHAV. 215–17 (2017).
[31] B. Han, et al., *Prescription Opioid Use, Misuse, and Use Disorders in U.S. Adults: 2015 National Survey on Drug Use and Health*, Annals of Internal Medicine, Vol. 167 No.5 (September 5, 2017).
[32] Seth P, Scholl L, Rudd RA, Bacon S. *Increases and Geographic Variations in Overdose Deaths Involving Opioids, Cocaine, and Psychostimulants with Abuse Potential – United States, 2015-2016.* MMWR Morb. Mortal. Wkly. Rep. ePub (March 29, 2018). See also, CDC, *Opioid Overdose, Prescription Opioid Overdose Data*, available at https://www.cdc.gov/drugoverdose/data/overdose.html
[33] *Id*.
[34] *Id*.

106. To date, prescription opioids have accounted for more American deaths than World War I, the Korean War, and the Vietnam War combined.

107. Over the next decade, the number of prescription opioid-related deaths is expected to exceed 650,000, outpacing the estimated number of deaths caused by breast and prostate cancers combined during the same period. To put this figure in context, that figure exceeds the approximately 620,000 Americans who lost their lives in the line of duty during the entire American Civil War.

108. Opioids could kill nearly as many Americans in a decade as HIV/AIDS has killed since that epidemic began in the early 1980s.

109. Nationwide, from 1997 to 2002, there was a 73%, 226%, and 402% increase in morphine, fentanyl, and oxycodone prescribing, respectively (in grams per 100,000 populations).

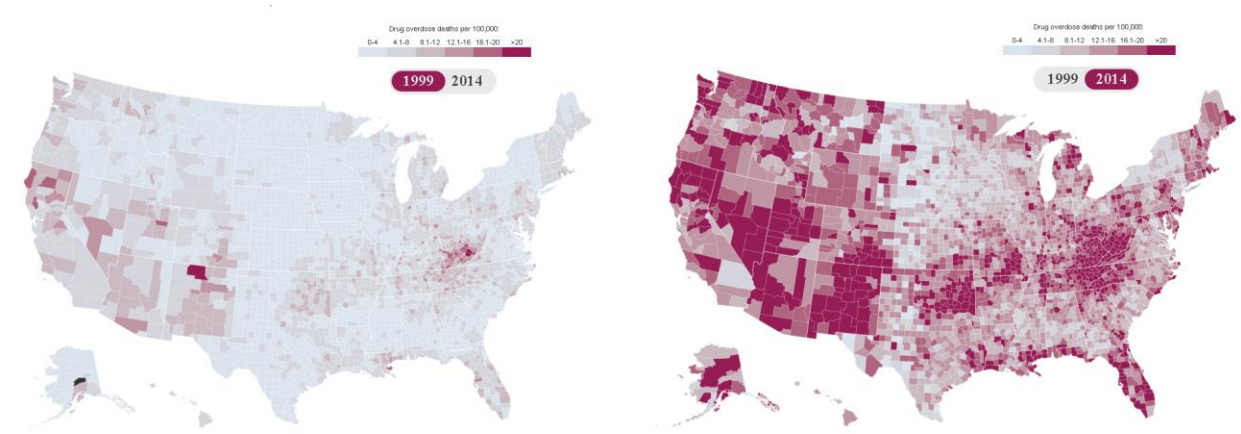
110. During that same period, hospital emergency department mentions for morphine, fentanyl, and oxycodone increased 113%, 641%, and 346%, respectively.

111. Mortality rates from opioid overdose have climbed dramatically. Since 1999, overdose deaths due to prescription opioids have continued to rise. And in 2002, unintentional overdose deaths from prescription opioids surpassed those from heroin and cocaine nationwide.

112. The crisis in opioid overdose deaths has reached epidemic proportions in the United States (33,091 in 2015), and currently exceeds all other drug-related deaths or traffic fatalities.

113. Thus far in 2017, 175 Americans have died every day because of the opioid epidemic.

114. The incredible increase in overdoses from 1999 to today is illustrated by the following graph:



https://www.theguardian.com/society/ng-interactive/2016/may/25/opioid-epidemic-overdose-deaths-map

B. Social, Economic, and Health Consequences of Prescription Opioid Abuse

115. The victims of the opioid epidemic, however, are not just those who die from overdoses. Prescription opioid abuse also imposes severe harm on those who live with addiction, their families, and their communities.

116. People suffering from opioid addiction often suffer from a variety of interlocking psychological ailments, including depression, lack of motivation, anxiety, and drug-seeking behavior. Addiction can thus wreak havoc on an individual's ability to complete daily tasks, to hold down a job, and to care for a family.

117. A recent Brookings Institution study examining the implications of the opioid crisis on the labor force suggests that the increase in opioid prescriptions could account for much of the decline in the labor force participation of "prime age men" (ages 25-54).[35]

[35] Alan B. Krueger, Princeton University, *Where Have All the Workers Gone? An Inquiry into the Decline of the U.S. Labor Force Participation Rate*. BROOKINGS PAPERS ON ECONOMIC ACTIVITY: BPEA CONFERENCE DRAFTS (2017), https://www.brookings.edu/wp-content/uploads/2017/09/1_krueger.pdf.

118. On any given day, 31% of prime age men not in the labor force report taking prescription pain medication, most likely opioid based. In fact, the true percentage is likely far higher than this self-reported number, due to the stigma and legal risk associated with narcotics.[36]

119. Opioid abuse also devastates families. When a family member is addicted to opioids, each family member is affected differently. The most vulnerable, however, are children.

120. Indeed, a child's vulnerability to opioids begins even before a child is born. Developing fetuses are vulnerable to substance use by the pregnant mother, as drugs such as opioids can easily cross the placenta and enter fetal blood circulation.

121. The number of children experiencing neonatal abstinence syndrome ("NAS"), a group of problems that occur in newborns exposed to opioids in utero, increased 383% during the period 2000-2012 (1.2 cases per 1000 hospital births in 2000 to 5.8 cases per hospital births in 2012).[37]

122. In addition, children whose parents have an opioid addiction may be neglected or require removal to foster care.

123. In communities across the country, including in the Social Services department of the Passamaquoddy Tribe–Pleasant Point, the number of children who have entered foster care due to parental drug use has increased in recent years. As a result, such Social Services departments and child welfare agencies have seen a dramatic increase in their caseloads. Such welfare agencies, however, are often severely underfunded. Social Services departments and child welfare agencies thus frequently lack sufficient resources to support drug treatment or parenting classes, or to fund community-based support for children of addicted parents.

---

[36] *Id.*

[37] Ctr. for Disease Control & Prevention, *Morbidity and Mortality Weekly Report – Incidence of Neonatal Abstinence Syndrome – 28 States, 1999–2013*, CDC.GOV (Aug. 12, 2016), https://www.cdc.gov/mmwr/volumes/65/wr/mm6531a2.htm.

124. The adverse effects of the opioid epidemic are not confined to addicted individuals or their families. To the contrary, the costs of the opioid epidemic radiate outward, and are borne by society at large.

125. The monetary costs of prescription opioid overdose, abuse, and dependence are staggering. The White House Council of Economic Advisers recently reported that, in 2015, "the economic cost of the opioid crisis was $504.0 billion, or 2.8 percent of the GDP that year."[38]

126. The total cost of the opioid crisis is so high, the White House Council of Economic Advisers emphasized, because of the multifaceted harms caused by prescription opioids. Among other things, the opioid epidemic has imposed significant costs on the healthcare system, and on the criminal justice system. It has also significantly reduced worker productivity, both as a result of addiction and incarceration.[39]

127. As staggering as a $504 billion annual cost might be, however, the actual current economic cost of the opioid epidemic is probably even higher. As one commentator noted, the White House's 2015 "estimate is probably low for 2016, given that drug and opioid overdose deaths spiked last year compared to 2015."[40]

C. The Rising Tide of the Heroin Epidemic

128. In addition to the costs directly imposed be prescription opioid abuse, the prevalence of prescription opioids in the United States has led to an unprecedented increase in heroin use. According to the Center for Behavioral Health Statistics and Quality, 914,000 people

---

[38] COUNCIL ECON. ADVISERS, THE UNDERESTIMATED COST OF THE OPIOID CRISIS 1 (2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/The%20Underestimated%20Cost%20of%20the%20Opioid%20Crisis.pdf.

[39] *Id.*

[40] German Lopez, *White House: One Year of the Opioid Epidemic Cost the US Economy More Than $500 Billion*, VOX.COM (Nov. 20, 2017), https://www.vox.com/science-and-health/2017/11/20/16679688/white-house-opioid-epidemic-cost.

in 2014 reported prior heroin use, a 145% increase from 2007. As a direct result of increased heroin use, heroin-related overdoses are spiking. In 2002, the rate of heroin-related overdose deaths in the United States was 0.7 per 100,000 people. By 2013, that rate had climbed to 2.7 per 100,000 people—a 286% increase.

129. Heroin use in the United States increased dramatically the period in which the country witnessed a rise in prescription opioid misuse. Data from the 2001-2002 and 2012-2013 National Epidemiologic Survey on Alcohol and Related Conditions-I and–III ("NESARC") showed prevalence of heroin use increased five-fold in the United States during the period between the two surveys.[41]

130. The parallel explosion in rates of prescription opioid abuse and rates of heroin abuse is no coincidence. The pathway from prescription opioids to heroin is well-documented, and well understood. People who are prescribed a prescription opioid, either by a well-meaning physician or through a pill mill, can find that their tolerance and dependence on opioids increases over time. At that point, the allure of heroin, which is chemically highly similar to prescription opioids—yet often cheaper and more readily available—can prompt an individual to begin heroin use.

131. Scientific studies indicate that the prescription opioid epidemic is, far and away, the key driver of new heroin users. People who report previous nonmedical prescription pain-reliever use are 19 times more likely to begin using heroin than the general population.[42] What is more, prescription opioid abuse, not heroin, is now the main pathway into opioid addiction. Fifty years ago, 80% of people who abused opioids initiated that abuse through heroin. By the 2000s,

[41] SS Martins et al., *Changes In Lifetime Heroin Use And Heroin Use Disorder: Prevalence From The 2001–2002 to 2012-2013 National Epidemiologic Survey on Alcohol and Related Conditions.* 74 JAMA PSYCHIATRY 445–55 (2017).
[42] Pradip K. Muhuri et al., *Associations of Nonmedical Pain Reliever Use and Initiation of Heroin Use in the United States*, SAMHSA CTR. FOR BEHAVIORAL STATS. & QUALITY (August 2013), https://www.samhsa.gov/data/sites/default/files/DR006/DR006/nonmedical-pain-reliever-use-2013.htm.

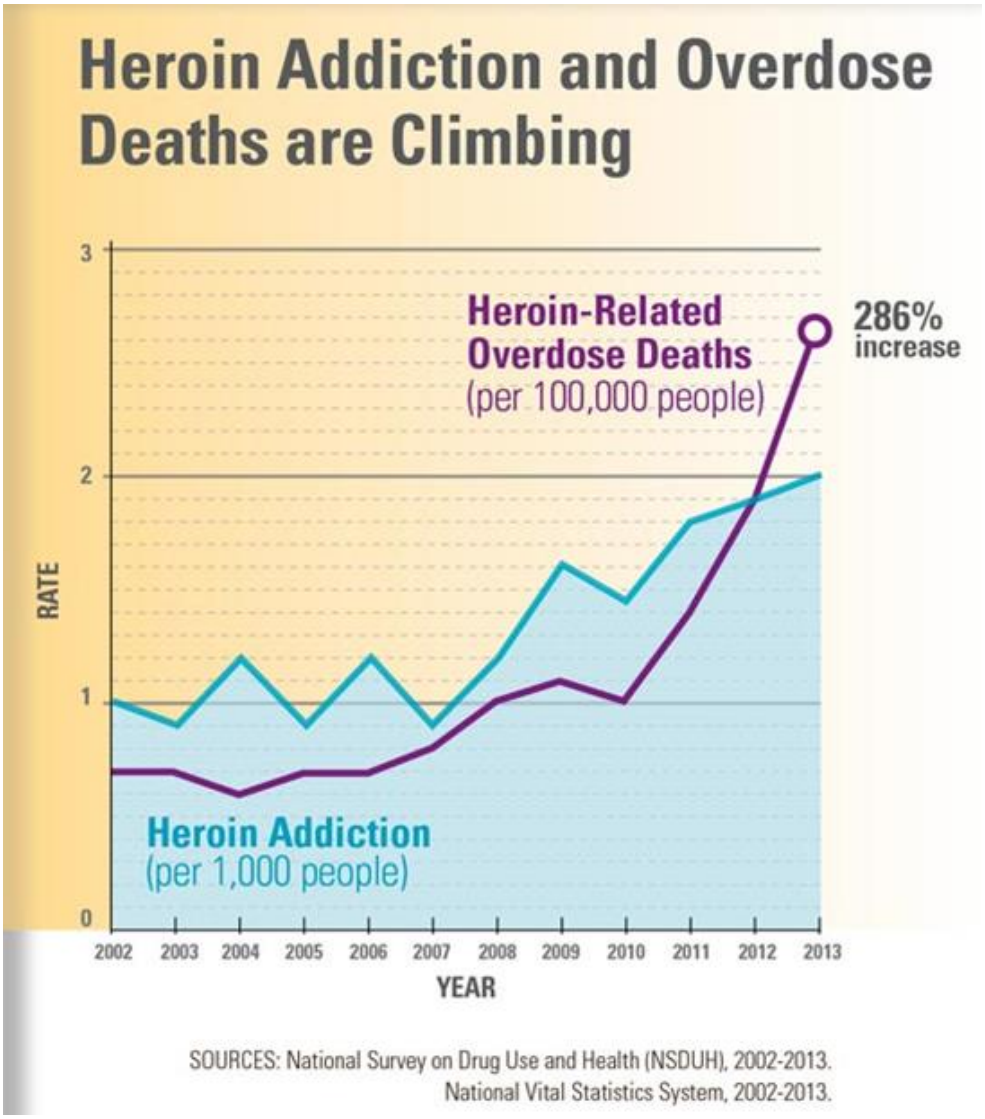
however, number had flipped on its head: 75% of people who began abusing opioids in the 2000s started through prescription opioids.[43]

132. Highlighting the link between prescription opioid use and heroin use, Washington University St. Louis Professor Theodore Cicero and his colleagues reported—in a letter to the *New England Journal of Medicine*—that after Purdue introduced a reformulated, purportedly "abuse resistant" strand of OxyContin, heroin use nearly doubled among previous opioid users. The authors noted that there was no evidence that OxyContin-addicted individuals ceased their drug use as a result of the abuse deterrent formulation. Rather, addicted individuals simply shifted to a new opioid: in many instances, heroin.[44]

133. That shift from prescription opioids to heroin is often a deadly one. As indicated in the chart below, heroin deaths escalated 4-fold in the five-year period comprising 2010-2015 alone:

[43] TJ Cicero et al., *The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years*, 71 JAMA PSYCHIATRY 81(2014).

[44] TJ Cicero et al., *Effect of Abuse-Deterrent Formulation of OxyContin*, 367 N. ENG. J. MED.187–89 (2012).



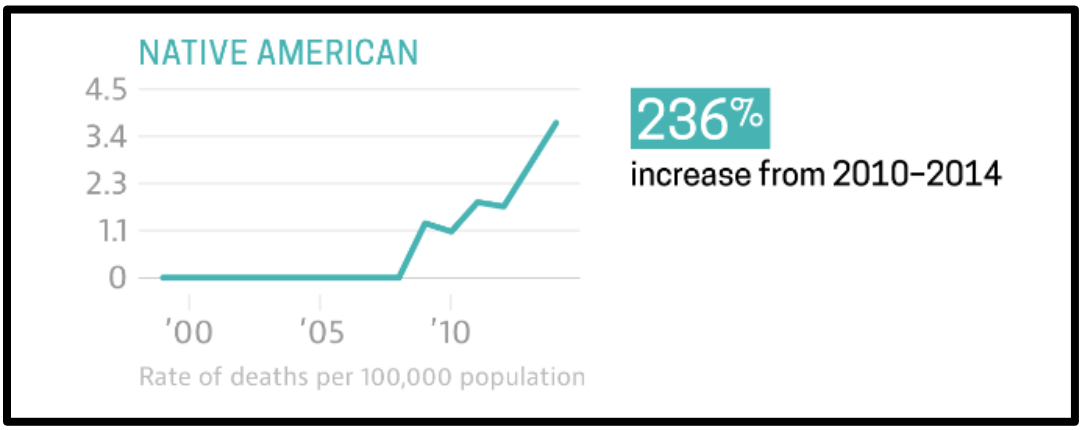
III. The Disproportionate Impact of the Opioid Crisis on Native Americans, Including the Passamaquoddy Tribe–Pleasant Point

134. The impact of the opioid crisis on Native Americans and Indian Tribes has been immense, and tribes across the United States have been particularly hard hit by the opioid epidemic.[45] In the State of Maine, the Plaintiff Passamaquoddy Tribe–Pleasant Point has suffered

[45] U.S. Senate, Committee on Indian Affairs, Oversight Hearing "Opioids in Indian Country: Beyond the Crisis to Healing the Community," Statements of Senator John Hoeven (R-ND), chairman of the Senate Committee on Indian Affairs, and Michael E. Toedt, MD, Chief Medical Officer, Indian Helath Service (March 14, 2018), available at

tremendous economic hardship from the impact of opioids upon the health and welfare of the Tribe's members and the resulting substantial increases in the Tribe's opioid-related costs and the negative economic impact on the Tribe's resources, programs, and services.

135. Native Americans and Indian Tribes, including the Passamaquoddy Tribe–Pleasant Point, have been disproportionately affected by the opioid crisis. American Indians are more likely to abuse or overdose on prescription painkillers. [46] Per capita, American Indians have the highest rate of opioid overdoses.[47] About 1 in 10 American Indians age 12 or older used prescription painkillers for nonmedical reasons in the past year, compared to 1 in 20 whites and 1 in 30 blacks.[48] Moreover, as the Indian Health Service has stated, the CDC data on opioids may underestimate the problem among American Indians as a result of racial misclassification leading to artificially lower rates through misidentification of American Indians.[49]



https://www.indian.senate.gov/sites/default/files/upload/HHS%20IHS%20testimony%20Opioids%20Indian%20Country%20SCIA%203-14-18%20revised.pdf.

[46] CDC Vitalsigns, *Prescription Painkiller Overdoses in the US* (November 2011), located at https://www.cdc.gov/vitalsigns/pdf/2011-11-vitalsigns.pdf.

[47] National Congress of American Indians, Policy Research Center, *Reflecting on a Crisis, Curbing Opioid Abuse in Communities* (October 2016), available at http://www.ncai.org/policy-research-center/research-data/prc-publications/PRCResearchUpdate_Annual2016.pdf.

[48] *Id.*

[49] US Medicine, *IHS grapples with pervasive prescription opioid misuse in tribal areas* (January 2012), located at http://www.usmedicine.com/clinical-topics/addiction/ihs-grapples-with-pervasive-prescription-opioid-misuse-in-tribal-areas.

136. In the State of Maine, the opioid epidemic continues to devastate rural and urban communities across the State.[50] Maine, where the Passamaquoddy Tribe-Pleasant Point reside, has one of the highest rates for the sale and use of prescription opioid painkillers in the United States,[51] as well as one of the highest increases in hospital emergency department admissions. From 2015 to 2016, for example, Maine experienced a 34% increase in emergency room admissions resulting from opioid overdoses.[52] It also has one of the highest rates of drug overdose mortality in the United States.[53]

137. Maine is among the top four states with the highest overdose death rates from prescription opioids.[54] From January 2016 (270 deaths) to January 2017 (359 deaths), Maine experienced a 33% increase in the number of drug overdose deaths.[55]

138. Defendants' false, deceptive and unfair marketing of prescription opioids, and their failure to stop plainly suspicious orders of opioids and diversion of opioid products is the proximate cause of the extraordinary financial burden their conduct has imposed upon the Passamaquoddy Tribe–Pleasant Point.

139. Accordingly, the Plaintiff Passamaquoddy Tribe–Pleasant Point hereby seeks to recover for its opioid-related damages, including its costs for: (a) medical care and treatment, (b) detox programs and facilities, (c) behavioral, mental-health services, and substance abuse

---

[50] Office of the Maine Attorney General, *Drug overdose deaths keep steady pace through first six months of 2017 with 185 deaths recorded through the end of June* (September 6, 2017), located at http://www.maine.gov/ag/news/article.shtml?id=765461.

[51] CDC, *Vital Signs: Overdoses of Prescription Opioid Pain Relievers United States, 1999-2008*, Morbidity and Mortality Weekly Report 2011; 60(43);1487-1492 (Maine's number of opioid prescriptions per 100 people is 82.2-95, which is among the highest in the nation).

[52] A. Vivolo-Kantor, et al., *Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses—United States, July 2016-September 2017*, CDC, Morbidity and Mortality Weekly Report, Vol. 67, No. 9, 279-285 (March 9, 2018).

[53] CDC, *Drug Overdose Death Data*, available at https://www.cdc.gov/drugoverdose/data/statedeaths.html.

[54] *Id.*, The others were West Virginia, Maryland, and Utah.

[55] CDC, *Provisional Counts of Drug Overdose Deaths, as of 8/6/2017*, available at https://www.cdc.gov/nchs/data/health_policy/monthly-drug-overdose-death-estimates.pdf.

counseling, (d) treatment and care for minors affected by parents and/or guardians suffering from prescription opioid-related addiction, dependence, overdose and death, (e) public safety programs, (f) education programs, and (g) lost productivity, among others.

140. Plaintiff Passamaquoddy Tribe–Pleasant Point further brings this civil action to eliminate or reduce the imminent threat to public health and safety of the Passamaquoddy Tribe caused by the opioid epidemic, to abate the nuisance caused by using opioid products that were foreseeable to Defendants and were sustained through Defendants' patterns of activity and directly resulting from their reckless, intentional and unlawful acts and omissions.

IV. Manufacturer Defendants' Fraudulent Marketing Campaign Regarding Opioids

141. The present-day opioid crisis was triggered by the opioid manufacturers ("Manufacturer Defendants"), each of whom produces one or more prescription opioid products.

142. The Manufacturer Defendants sought to expand the market for their opioids beyond the treatment of terminally ill cancer patients or patients severely injured, to the treatment of the vast market of patients with chronic, non-cancer pain such as lower back pain, arthritis, tooth ache, and other common ailments.

143. To expand the markets for their opioid products, the Manufacturer Defendants designed and undertook a marketing campaign based upon false and incomplete information to persuade physicians, health professionals, patients, and others to increase prescriptions of their opioid products based the claim that they were safe and effective for the treatment of patients with chronic pain not caused by cancer and who are not terminally ill.

144. Beginning in the 1980s, the Manufacturer Defendants introduced new opioid drugs and sought to maximize the market for them by inducing physicians, health professionals, and others to increase prescriptions of their opioid products. They were able to achieve this goal

through numerous fraudulent marketing techniques which were based on numerous false representations and omissions regarding the safety and efficacy of their opioid products.

145. These techniques included (a) distorting the medical literature on opioids by deceitfully and widely promoting a few cherry-picked articles and a letter to the editor— which were later disavowed—as support for their false claims that opioids present a low risk of addiction, (b) funding purportedly neutral professional organizations to convince medical doctors and the public, contrary to what doctors and the public had previously been taught, that opioids were safe and not addictive, (c) lavishing large fees, honoraria and other perks on medical doctors characterized as "opinion leaders" to give speeches extolling and promoting the falsehood that opioids are safe and effective for common pain, (d) funding and distributing publications that were deceptive about opioids, and other unscrupulous marketing techniques.

146. The Manufacturer Defendants, individually and as a group, encouraged medical doctors to prescribe opioids more liberally and reassured them, based on false evidence, that the risk of becoming addicted to prescription opioids was less than one percent. That figure was tragically wrong. Recent studies reveal that as many as 56% of patients receiving long term opioid painkillers progress to addictive opioid use—including patients with no prior history of addiction.

147. The Manufacturer Defendants knew that patients treated with opioids, once they became addicted, would feel compelled to purchase more opioid products and would lack sufficient willpower to stop purchasing opioid products. The Manufacturer Defendants also knew that given enough time on opioids, a patient would need higher and higher doses to stave off the ever-looming and life-threatening effects of opioid withdrawal, the only remedy for which is more opioids.

148. Nevertheless, despite knowing that their prescription opioid products were as dangerous as heroin, opium, or morphine, the Manufacturer Defendants misrepresented these risks and thereby fostered addiction as a central component of their business model with a total disregard for the harms caused by opioid misuse, addiction, and diversion.

149. The Manufacturer Defendants' misinformation campaign worked as intended. Across the country, demand for prescription opioids exploded. Doctors and medical professionals, swayed by the Manufacturer Defendants' sophisticated propaganda machine, began prescribing prescription opioids for ailments ranging from headaches to neck pain to fibromyalgia. This unleashed a wave of misuse and addiction—increasing the demand for opioids yet further. As an inevitable consequence, the Manufacturer Defendants' profits soared.

A. Manufacturer Defendants Made Numerous False Representations Regarding the Safety and Efficacy of their Opioid Products

i. They Falsely Represented that the Risk of Addiction from their Opioid Products Was Low

150. The onset of the Manufacturer Defendants' campaign of deception regarding the addictive nature of opioids was rooted in two pieces of purportedly "scientific" evidence. The first was a five-sentence letter to the editor published in 1980 in the *New England Journal of Medicine*. The letter was drafted by Hershel Jick, a medical doctor at Boston University Medical Center, with the help of a graduate student, Jane Porter. It noted, anecdotally, that a review of "current files" did not indicate high levels of addiction among hospitalized medical patients who received narcotic preparation treatment. *In full*, the letter reads:

> Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well-documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients, Percodan in one, and

> hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

Addiction rate in patients treated with narcotics, 302(2) New Eng. J. Med. 123 (Jan. 10, 1980).

151. The second piece of "evidence" they promoted was a 1986 study by Russell Portenoy, MD, who was then 31 years old, in the medical journal *Pain.* The study, which had a patient cohort of only 38 patients, claimed that opioids could be used for long periods of time to treat non-cancer related chronic pain without any risk of addiction. The rationale behind the study was that patients in pain would not become addicted to opioids because their pain drowned out the euphoria associated with opioids. The study concluded that opioids should be freely administered to patients with fibromyalgia, headaches, finicky backs, and a host of other issues. According to Dr. Portenoy and his co-author, Dr. Kathleen Foley, "opioid maintenance therapy can be a safe, salutary and more humane alternative … in those patients with intractable non-malignant pain and no history of drug abuse."[56] Dr. Portenoy's study also cited Dr. Jick's one-paragraph letter to the *New England Journal of Medicine*.

152. Portenoy went on to serve as one of the pharmaceutical industry's most vocal advocates, regularly appearing at conferences and gatherings of medical professionals to promote the use of opioids for chronic, long-term pain.

153. In the years that have followed, both the *New England Journal of Medicine* letter and Portenoy's 1986 study have been expressly disavowed. Neither actually demonstrates that opioids can be safely prescribed for long-term, chronic pain.

154. In a taped interview in 2011, Portenoy admitted:

[56] Portenoy RK, Foley KM, *Chronic use of opioid analgesics in non-malignant pain: report of 38 cases*, 25 Pain 171 (1986).

> I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite. I would cite 6 to 7 maybe 10 different avenues of thought or evidence, ***none of which represents real evidence***. And yet what I was trying to do was to create a narrative so that the primary care audience would look at this information in toto and feel more comfortable about opioids in a way they hadn't before … Because the primary goal was to de-stigmatize, ***we often left evidence behind***."
>
> ***It was clearly the wrong thing to do*** and to the extent that some of the adverse outcomes now are as bad as they have become in terms of endemic occurrences of addiction and unintentional overdose death, it's quite scary to think about how the growth in that prescribing driven by people like me led, in part, to that occurring.[57]

155. As to the *New England Journal of Medicine* letter, Dr. Jick, in an interview with Sam Quinones decades after the letter was published, stated: "[t]hat particular letter, for me, is very near the bottom of a long list of studies that I've done. It's useful as it stands because there's nothing else like it on hospitalized patients. But if you read it carefully, it does not speak to the level of addiction in outpatients who take these drugs for chronic pain."

156. *The New England Journal of Medicine* itself has since disavowed the letter, stating "[the letter] was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy." 376 *New Eng. J. Med*. 2194, 2194–95 (2017). "We believe," the journal stated "that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy." *Id.*

157. Indeed, the letter—because it was just a letter—did not describe how the data was gathered, the duration of the patients' treatment, or the purpose behind their treatment in the first

[57] Live interview with Dr. Russell Portenoy. Physicians Responsible for Opioid Prescribing. https://www.youtube.com/watch?v=DgyuBWN9D4w. Accessed December 3, 2017 (emphases added). See also, Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, The Wall Street Journal (Dec. 17, 2012).

place. But the *New England Journal of Medicine* is one of the premier medical journals in the country. And, given the journal's prestige, the five-sentence letter, combined with Portenoy's later study, was exactly what opioid manufacturers needed to push their products.

158. In the years following the publication of the *New England Journal of Medicine* letter, and the publication of Russell Portenoy's 1986 study, the Manufacturer Defendants introduced multiple new highly addictive opioid products onto the market. Those new drugs included: Purdue's MS Contin (introduced 1987) and OxyContin (1995), Janssen's Duagesic (1990), Nucynta (2008), and Nucynta ER (2011), Cephalon's Actiq (1998) and Fentora (2006), Endo's Opana and Opana ER (2006), and Insys' Subsys (2012).

159. To expand the markets for those new products, the Manufacturer Defendants engaged in a concerted push to convince doctors and the general public that opioids were safe and effective for long-term pain relief. In large part, the Manufacturer Defendants relied upon Russell Portenoy, MD, the author of the 1986 *Pain* study. Because Portenoy's study dovetailed perfectly with the Manufacturer Defendants' marketing strategy, within a decade, Portenoy was financed by "at least a dozen companies, most of which produced prescription opioids."[58]

160. By enlisting concept peddlers like Dr. Portenoy to promote opioid analgesics, the Manufacturer Defendants successfully promoted the myth that opioids could be liberally prescribed for non-cancer related chronic pain, without any risk of addiction.

161. The Manufacturer Defendants lavishly funded these concept peddlers. In turn, these concept peddlers would speak at academic conferences to primary care physicians in an effort to de-stigmatize opioids and encouraged liberal prescription of narcotics for the treatment non-cancer related chronic pain. Invariably, the key piece of "data" cited in support of the

[58] Meier B., *Pain Killer: A Wonder Drug's Trail of Addiction and Death*, New York, NY: St. Martin's Press; 2003.

proposition that opioids could be safely used to treat chronic pain was the *New England Journal of Medicine* article by Portnoy.

162. Each of the Manufacturer Defendants claimed, and have continued to claim, that the risk of addiction from their opioid products is extremely low or non-existent, even though the published medical literature and scientific evidence does not support their claims.

163. Defendant Purdue, for example, misrepresented the risk of addiction from use of its prescription opioids by repeatedly citing the Porter/Jick letter in its promotional and educational materials to support its OxyContin product. Further, Purdue's sales representatives marketed OxyContin to doctors as safe and effective for long term treatment of chronic non-cancer pain. These misrepresentations significantly increased the number of prescriptions being written for OxyContin.

164. Defendant Endo misrepresented on several of its websites, in training materials for sales representatives, and in publications that addiction to opioids is rare.

165. Defendant Janssen misrepresented on its websites and in print materials that addiction from the use of opioid products is overestimated and occurs only in a small percentage of patients.

166. Defendant Cephalon sponsored Continuing Medical Education presentations and patient guidebooks which falsely claimed that addiction to opioids is rare.

167. Defendant Actavis falsely claimed in promotional materials, patient guides, and training materials that the risks of addiction to its opioid products are minimal.

168. Defendant Mallinckrodt falsely claimed in promotional materials on its website and other communications that its opioid products only rarely caused addiction.

ii. The Manufacturer Defendants made numerous other false claims regarding the safety and efficacy of their opioid products.

169. The Manufacturer Defendants have also deceitfully peddled a number of other false claims regarding the safety and efficacy of their opioid products, including the following.

170. They coined and peddled the term "pseudo-addiction" to claim that patients who were exhibiting the classic signs of addiction—for example, compulsively seeking higher and higher doses of opioids to obtain pain relief—were suffering from under-treatment of their pain and the solution was to prescribe even more opioids. Nevertheless, despite the fact that 80 percent of the global opioid supply is consumed in the United States, concept peddlers, front groups, and the Manufacturer Defendants continue to maintain that pain is undertreated.

171. They misrepresented and minimized the difficulties of treating withdrawal symptoms from prolonged use of opioids by falsely claiming that patients with such symptoms were merely dependent and not addicted and that such dependence could be easily treated with a brief period of tapering (lowering) their dose of opioids.

172. They falsely claimed that opioid doses could be safely increased to higher dosage levels without warning about the risks to health, including increased tolerance, dependence, and addiction, which are associated that higher doses of opioids. Based on these false claims, they aggressively pushed physicians to prescribe higher doses of opioids for patients with pain.

173. They falsely claimed that that long-term opioid use could improve a patient's functioning and quality of life despite clinical evidence and the existing medical literature to the contrary and despite warning from the FDA that such claims were misleading.

174. They have falsely promoted new formulations of their opioid products as "abuse deterrent" as a basis to claim their products are less subject to misuse and addictive when, in fact, as the CDC Guidelines for Prescription Opioids confirm, for there are no scientific studies which support such claims.

175. They have promoted the falsehood that other forms of pain relief—for example, NSAIDs (e.g., Motrin)—posed higher risks to patient health than their opioid products.

iii. The Manufacturer Defendants Paid "Opinion Leaders" To Spread False Representations Regarding Their Opioid Products

176. The Manufacturer Defendants cultivated and paid a select group of physicians known as "opinion leaders" to give the appearance of scientific and medical legitimacy in support of misleading claims regarding the safety and efficacy of their opioid products for treatment of chronic, non-malignant pain.

177. Dr. Russell Portnoy was one of the principal "opinion leaders" who served as a top spokesperson for the opioid manufacturers. Dr. Portnoy received lavish financial support from defendant Purdue to support the misleading claims that, among others, opioids present a low risk of misuse and addiction and that opioids could be safely prescribed for long-term use.

178. Dr. Portnoy supported these false claims in paid speeches, published papers and books, and in being cited in the Manufacturer Defendant marketing materials.

179. Dr. Portnoy served as a Director on one of the Manufacturer Defendants' front groups, the American Pain Foundation (APF). In this capacity he assisted in promoting the Manufacturer Defendants' false marketing claims regarding the safety and efficacy of their opioid products.

180. Dr. Portnoy has recently admitted that in his capacity as a spokesperson for the Manufacturer Defendants he minimized the risks of opioids and gave numerous misleading speeches about addiction, pain management, and opioid therapy.

181. Other phony "opinion leaders" paid by the Manufacturer Defendants to promote their misleading claims include Dr. Lynn Webster, Dr. Perry Fine, and Dr. Scott Fishman.

182. Dr. Webster received substantial monies from Cephalon, Endo, and Purdue to author Continuing Medical Education presentations which presented misleading information about opioids and minimized their risks.

183. Dr. Fine received payment from Defendants Purdue, Endo, and Janssen, among others, delivered educational talks, served on the boards of phony front groups such as the American Pain Society, and authored articles, in which he minimized the risks of misuse and addiction related to opioid products.

184. Dr. Fishman likewise received substantial payments from the Manufacturer Defendants and authored various publications, guides on opioid prescribing, participated in CMEs, in which he minimized and misrepresented the risks related to opioids.

iv. The Manufacturer Defendants Marketed Their Misrepresentations Through Front Groups.

185. In addition to funding and supporting concept peddlers like Portenoy, the Manufacturer Defendants funded multiple innocuously named front groups to convince doctors and medical professionals that opioids could safely be used as a long-term treatment for chronic pain.

186. Those organizations included the American Pain Foundation (which received nearly 90% of its funding from the drug and medical device industry, including Manufacturer Defendants); the American Academy of Pain Management (which received funding from Manufacturer Defendants Endo, Janssens, and Purdue); and the American Pain Society.

187. All of these purportedly neutral, industry-funded organizations took aggressive stances to convince doctors and medical professionals that America was suffering from an epidemic of untreated pain—and that opioids were the solution.

188. For example, the American Pain Foundation, of which Dr. Portenoy was a director, urged tracking of what they called an epidemic of untreated pain. The American Pain Society, of which he was president, campaigned to make pain what it called the "fifth vital sign" that doctors should monitor, alongside blood pressure, temperature, heartbeat and breathing.[59]

189. In 1996, the American Pain Society and the American Academy of Pain Management, both funded almost entirely by the Manufacturer Defendants, issued a "landmark consensus," written in part by Portenoy, claiming that there is little risk of addiction or overdose in pain patients. The consensus cited the "less than 1 percent" addiction figure and the Jick letter.

190. In reality, however, the risk of addiction is as high as 56%. Martell BA, O'Connor PG, Kerns RD, Al E., *Systematic review: opioid treatment for chronic back pain: prevalence, efficacy, and association with addiction*, 146 Ann. Intern. Med. 116 (2007).

191. Other front groups include the Alliance for Patient Access ("APA") which receives the bulk of its financial support from opioid manufacturers including Endo, Mallinckrodt, Pudue, and Cephalon. In addition, APA Board Members have received substantial sums of money from the Manufacturer Defendants, including Endo, Insys, Pudue and Cephalon. The APA has published misleading white papers promoting opioid products for treatment of chronic, non-cancer pain. It has also lobbied Congress in opposition to legislation which would establish prescription drug monitoring programs (PMPs).

192. The U.S. Pain Foundation and American Geriatrics Society are other front groups who receive much of their funding from the Manufacturer Defendants and who take positions favorable to the interests of the Manufacturer Defendants by issuing guidelines, lobbying

[59] On June 16, 2016, at its annual meeting in Chicago, the American Medical Association (AMA)—a legitimate medical organization—urged physicians to eliminate pain as the fifth vital sign.

Congress, appearing at conferences, and other activities which promote the use of the Manufacturer Defendants opioid products for treatment of chronic, non-cancer pain while minimizing or omitting the risks associated with the safety and efficacy of their opioid products.

V. Manufacturer Defendants' Misrepresentations Regarding Their Specific Products

193. In addition to funding massive propaganda campaigns as to the safety of opioids, generally, each of the Manufacturer Defendants actively engaged in deceptive conduct with respect to their opioids, in particular. This deception, importantly, included deceiving the FDA about key qualities of their drugs.

A. FDA Approval Process

194. Pursuant to the Federal Food, Drug and Cosmetic Act ("FDCA"), new pharmaceutical drugs may not be marketed in the United States until the FDA determines that the drug is "safe for use" and effective for all "conditions prescribed, recommended, or suggested" on a drug's label. *See* 21 C.F.R. 99.103; *see also* 21 C.F.R. §201.5.

195. A company seeking to bring a new pharmaceutical drug to market in the United States must first go through a three-step FDA approval process:

a) *First*, the sponsoring company must conduct laboratory testing in animals to determine whether the drug will be relatively safe and, to some extent, effective. If animal testing indicates that the drug or compound is relatively safe, the company then submits an investigational new drug ("IND") application to the FDA to gain approval to test the product with human subjects;

b) *Second*, the sponsoring company must conduct "clinical trials" on human subjects. Clinical trials are carried out sequentially in three phases—Phase I, II, and III

studies. Each phase increases the number of subjects, and is designed to test for safety and efficacy of the drug for specific uses and patient populations; and

c) *Third,* after the clinical trials are completed, the company compiles the data and analysis into a new drug application ("NDA"). FDA then reviews the NDA, focusing on three major potential concerns: (1) safety and effectiveness in the drug's proposed use; (2) appropriateness of the proposed labeling; and (3) adequacy of manufacturing methods to assure the drug's strength, quality, and identity. After evaluating the NDA, the FDA will make the decision whether to approve or reject the drug.

196. When a drug is approved by the FDA, it means the drug manufacturer has satisfied the regulatory requirements set forth in the Food Drug and Cosmetic Act ("FDCA"). It does not mean that the drug meets all state law requirements, or that it can be promoted for all uses in all populations.

197. Though the FDA plays an important role in approving drugs for use, its role is limited by the fact that it does not conduct its own clinical trials. The FDA must therefore rely heavily on the representations and reports made by the sponsoring company. For example, in the context of efficacy, the FDA can deny an application only if it finds the *application* lacks "substantial evidence that the drug will have the effect it purports or is represented to have[.]" *See* 21 U.S.C. § 355(d)(5).

198. The FDA's role is similarly circumscribed with respect to drug labeling. The FDA does not draft drug labels. Instead, the drug manufacturer submits proposed labeling and, unless the FDA finds, under FDCA standards, that the label is misleading, it must approve it. 21 U.S.C. § 355(d).

199. Much of the FDA approval process, then, hinges on the good-faith, honest representations of the sponsoring company. And the duties of a drug company to act in good faith do not end with the approval process. To the contrary, even after the FDA approves a drug, the company manufacturing the drug continues to bear the responsibility of ensuring that the drug is manufactured, promoted, and labeled correctly.

200. Towards that end, sections 502(a) and 201(n) of the FDCA (21 U.S.C. §§ 352(a), 321(n)) impose on drug manufacturers an ongoing duty to fully and accurately disclose information in their possession relating to the efficacy of a drug—as well as information relating to adverse events associated with that drug's use. These disclosures must appear in the drug's package insert, other labeling, and promotional materials.

201. Sections 502(a) and 201(n) of the FDCA (21 U.S.C. §§ 352(a) and 321(n)) further prohibit drug manufacturers from making misleading statements about the efficacy of a drug, from minimizing the risks of adverse events associated with that drug's use, or from making misleading claims that a drug is safer or more effective than other available medications.

202. The indications and dosages approved by the FDA are set forth in the drug's labeling, the content of which is also approved by the FDA.

203. The Food, Drug and Cosmetic Act defines "label" as "a display of written, printed, or graphic matter upon the immediate container of any article ..." *See* 21 U.S.C. § 321(k).

204. Furthermore, 21 C.F.R. 202.1(l)(2) states:

> Brochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints and similar pieces of printed, audio, or visual matter descriptive of a drug and references published (for example, the 'Physicians' Desk Reference') for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or

> distributor are hereby determined to be labeling as defined in section 201(m) of the act.

205. A manufacturer's statement that a drug is "effective" or "works" or "has been proven to …" is understood to mean that well-controlled clinical studies support the use. Such a statement without clinical trial proof is misleading and a violation of a manufacturer's obligation to disclose the necessary information. *See* 21 C.F.R. § 99.205.

206. FDA also regulates the advertising and promotion of prescription drugs under the FDCA. FDA carries out this responsibility by ensuring that prescription drug advertising and promotion is truthful, balanced, and accurately communicated. FDA regulations require that promotional labeling and advertisements be submitted to the FDA at the time of initial dissemination (for labeling) and initial publication (for advertisements). The FDCA defines labeling to include all labels and other written, printed, or graphic matter accompanying an article. For example, promotional materials commonly shown or given to physicians, such as sales aids and branded promotional items, are regulated as promotional labeling.

B. Each Manufacturer Defendant Flouted This Process For its Particular Product(s)

207. Every Manufacturer Defendant flouted its duties under the FDCA for its particular product. Once Manufacturer Defendants were found to be in violation of the FDCA, the Manufacturer Defendants indirectly marketed through third parties to alter the way doctors viewed and prescribed opioids. They disseminated through these third parties the unproven and deceptive messages that opioids were safe for the treatment of non-cancer related chronic pain, that opioids were virtually non-addictive and that opioids were woefully under-prescribed to the detriment of patients who were needlessly suffering to avoid FDA regulation and oversight.

208. The Manufacturer Defendants did so by sponsoring pro-opioid front groups who published misleading prescription guidelines, articles, and Continuing Medical Education sessions

("CMEs"), and paid physicians thousands of dollars every year to publicly opine on the safety, efficacy, and non-addictive nature of opioids for a wide variety of uses.

i. Purdue

209. Purdue manufactures, among other opioids, OxyContin. OxyContin is a so-called "delayed release" pill, in which doses of opioids are released into the bloodstream in specified amounts over a specified period of time.

210. Purdue believed that OxyContin's "delayed release" mechanism was a game-changer, because (according to Purdue) one pill could provide the user with complete pain relief for 12 hours. That claim was front-and-center in Purdue's marketing materials. When Purdue launched OxyContin in the mid-1990s, it did so with the express claim that "One dose relieves pain for 12 hours, more than twice as long as generic medications."[60]

211. Purdue also claimed, repeatedly, that OxyContin's controlled release mechanism rendered the pill both effective and non-addictive.

212. Those claims were wrong. Indeed, when evaluating the efficacy of OxyContin in Purdue's 1995 NDA, the FDA's medical review officer concluded that OxyContin had not been shown to have a significant advantage over conventional, immediate-release oxycodone taken 4 times daily other than a reduction in frequency of dosing.

213. Despite this, Purdue continued to claim that OxyContin's delayed release mechanism rendered it less addictive, less subject to abuse and to diversion into illegal channels, and less likely to build opioid tolerance and cause withdrawal symptoms than predecessor drugs.

[60] Harriet Ryan, *et al., "You Want A Descripton of Hell?" OxyContin's 12-Hour Problem,* The Los Angeles Times (May 5, 2016).

214. Initially, OxyContin was available in 10 mg, 20 mg, 40mg, and 60 mg tablets. 80 mg and 160 mg tablets were introduced in 1997 and 2001, respectively.

215. Any dose of OxyContin above 40mg can be deadly for a non-opioid tolerant individual.

216. Purdue spread misinformation to doctors about physical addiction, asserting that opioid seeking patients were not physically addicted, but suffered from pseudo-addiction caused by the under-treatment of pain.

217. Upon information and belief, Purdue introduced different dosage levels with the specific intent that patients would become addicted and subsequently graduate to a higher dosage level, into perpetuity. One key promotional message for OxyContin was that it was the drug "to start and to stay with."

218. Purdue claimed that OxyContin's delayed release formula would make it less susceptible to abuse, because the delayed release formula foreclosed a rapid release of oxycodone. At the same time, Purdue included directions, in the form of a safety warning on OxyContin, on how crushing OxyContin would result in a rapid release of oxycodone, thereby circumventing the delayed release formula.

219. Purdue intentionally, fraudulently, and maliciously misrepresented to consumers and doctors alike that OxyContin was an opioid that provided 12 hours of pain relief, despite explicit knowledge to the contrary.

220. Upon information and belief, even before OxyContin was approved by the FDA in 1996 for marketing and sales in the United States, Purdue had significant information indicating that OxyContin does not treat a patient's pain for 12 hours. Information in Purdue's possession included a clinical study at hospitals in Puerto Rico in 1989 during which more than a third of the

study's subjects began complaining about pain in the first 8 hours, and about half required more medication before the 12-hour mark.

221. Upon information and belief, Purdue was incentivized to cling to its 12-hour claim of pain relief in order to protect its revenue stream because many available generic competitors successfully treated pain for less than 12-hour intervals. Without the 12-hour of pain relief claim, OxyContin did not stand out from its competitors, which obviated the need for doctors to continue prescribing OxyContin over available less-expensive alternatives.

222. Upon information and belief, when Purdue began receiving reports from physicians, sales representatives, and independent researchers that OxyContin did not last 12 hours, it nevertheless clung to its 12-hour of pain relief claim. Instead of reconsidering its claims, Purdue instead recommended that doctors prescribe higher doses of OxyContin rather than more frequent doses. Upon information and belief, Purdue deployed a team of hundreds of sales representatives to refocus physicians on 12-hour dosing, with company executives noting in internal documents that any consideration of more frequent dosing "needs to be nipped in the bud. NOW!"

223. As a result, patients taking OxyContin experienced higher highs, but also suffered much lower lows. Patients on whom OxyContin did not last the full 12 hours experienced agonizing pangs of acute withdrawal symptoms, and eventually became physically dependent of opioids and addicted. That, in turn, increased patients' propensity to use opioids other than as prescribed.

224. By claiming that OxyContin offered 12 hours of relief, Purdue was able to include more oxycodone than any prescription opioids at that time. In fact, OxyContin is twice as potent as morphine.

225. From 1996 to 2001, Purdue conducted more than 40 national pain-management and speaker training conferences at lavish resorts in Florida, Arizona, and California. More than 5000 physicians, pharmacists, and nurses attended these all-expenses-paid symposia, where they were recruited and trained for Purdue's national speaker bureau with the intent of influencing prescribing patterns towards prescribing opioids more liberally for non-cancer related chronic pain.

226. During that time, Purdue funded more than 20,000 pain-related educational programs through direct sponsorship or financial grants. In so doing, Purdue exerted enormous influence on physicians' prescribing practices throughout the country.

227. One of the cornerstones of Purdue's marketing plan was the use of sophisticated marketing data to influence physicians' prescribing patterns towards prescribing opioids more liberally for non-cancer related chronic pain.

228. Purdue (in an innovation that, on information and belief, was copied by other Manufacturer Defendants) compiled prescriber profiles on individual physicians detailing their prescribing patterns, in an effort to influence doctors' prescribing patterns towards prescribing opioids more liberally for non-cancer related chronic pain.

229. Through these profiles, Purdue (and, on information and belief, other Manufacturer Defendants) could, and can, identify the highest and lowest prescribers of particular drugs in a single zip code, county, state, or the entire country.

230. One of the critical foundations of Purdue's marketing plan for OxyContin was to target the physicians who were the highest prescribers for opioids across the country.

231. Purdue's prescriber database also helped identify physicians with large numbers of chronic-pain patients and helped identify which physicians were simply the most frequent prescribers of opioids and, in some cases, the least discriminate prescribers.

232. A lucrative bonus system encouraged Purdue's sales representatives to increase sales of OxyContin in their territories, resulting in a large number of visits by said sales representatives to physicians with high rates of opioid prescriptions, as well as a multifaceted "information" campaign aimed at high volume opioid prescribers. In 2001, in addition to the average sales representative's annual salary of $55,000, annual bonuses averaged $71,500, with a range of $15,000 to nearly $240,000.

233. Purdue paid $40 million in sales incentive bonuses to its sales representatives in 2001.

234. From 1996 to 2000, Purdue increased its internal sales force from 318 sales representatives to 671, and its total physician call list from approximately 33,400 to 44,500 to approximately 70,500 to 94,000 physicians. Through its sales representatives, Purdue used a patient starter coupon program for OxyContin, providing patients with a free limited-time prescription for a 7-day to 30-day supply. When the program was discontinued, approximately 34,000 coupons had been redeemed nationally.

235. Purdue also distributed to health care professionals branded promotional items such as OxyContin fishing hats, stuffed plush toys, and music compact discs (''Get in the Swing With OxyContin''). That "swag" strategy was, according to the DEA, unprecedented for an opioid regulated under Schedule II of the CSA.

236. By getting more "non-pain" specialist physicians to prescribe opioids, and by equating the prescription of opioids to compassion for those in pain, Purdue pulled off a

remarkably brilliant marketing campaign that was successful in removing the dangerous stigma surrounding its opioid drugs.

237. In much of its promotional campaign—in literature and audiotapes for physicians, brochures and videotapes for patients, and its ‘‘Partners Against Pain’’ website—Purdue claimed that the risk of addiction from OxyContin was extremely small.

238. In addition, Purdue provided two promotional videos to physicians that, according to FDA, appear to have made unsubstantiated claims and minimized the risks of OxyContin. The first video was available for about 3 years without being submitted to FDA for review.

239. In 2003, the FDA issued a warning letter to Purdue for spreading inaccurate information in OxyContin advertisements, and for failing to inform the public of important safety information about the drug. The letter found Purdue was in violation of the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 331(a) and (b), 352 (n).

240. While Purdue did withdraw the offensive promotional materials, rather than distributing a “Dear Healthcare Professional” (DHP) letter correcting the misinformation or altering the labeling for OxyContin, Purdue doubled down and instructed their sales force to "refocus" physicians when they learn that the physician was misinformed regarding the addictive qualities of their products.

241. The misinformation Purdue disseminated throughout the United States violated federal criminal law. On May 9, 2007, Defendant Purdue pleaded guilty, in federal court, to violations of 21 U.S.C. 331(a) and 331 (a)(2) for marketing and promoting OxyContin as less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.

242. Purdue thus knowingly misbranded OxyContin, and knowingly introduced misbranded OxyContin into interstate commerce, with the intent to defraud or mislead the medical community and consumers into believing OxyContin was less addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal than other pain medications.

243. Following its guilty plea, Purdue pivoted its promotion of OxyContin. De-emphasizing direct promotion, Purdue began to work primarily through patient advocacy organizations—or "Front Groups"—posing as neutral and credible professional organizations. In so doing, Purdue was able to deliberately mislead the medical community and the general public while avoiding FDA violations that would have been issued if it had conducted the same promotional campaigns directly.

244. The American Pain Foundation ("APF"), upon information and belief, received more than $10 million in funding from opioid manufacturers from 2007 through 2012. The primary opioid manufacturer contributors were Purdue and Endo. The APF, founded in 1997 described itself as the nation's largest advocacy group for pain patients.

245. APF published numerous guides and brochures for patients, doctors, and policymakers that minimized the risks of addiction and exaggerated the benefits associated with prescription opioids, including but not limited to the "Policymaker's Guide," sponsored by Purdue, which sought to dispel the "myth" that opioid pain medication leads to addiction.

246. At the heart of APF's messaging was that the risk of opioid addiction was overblown and opioids were underused as a treatment for pain. In December 2011, a ProPublica investigation found that in 2010, nearly 90% of APF's funding came from the drug and medical device community, including Manufacturer Defendants. On May 8, 2012 the U.S. Senate Finance

Committee sent a letter APF inquiring about its ties to drug manufactures. That very same day, APF announced it was ceasing operations, effective immediately.

247. Purdue also funded "Responsible Opioid Prescribing," a guide sponsored by the Federation of State Medical Boards ("FSMB") and authored by Dr. Scott Fishman, the former chairman and president of the now defunct APF in 2007. The guide was ultimately disseminated to 700,000 practicing doctors. A June 8, 2012 letter submitted by FSMB to the Senate Finance Committee disclosed that Purdue paid $40,000 to fund the production of the guide. Purdue also paid the FSMB at least $822,400 from 1997-2012.

248. The "Responsible Opioid Prescribing" guide promoted the use of opioid pain relievers for both acute and chronic pain and severely minimized the risk of addiction, even claiming that opioids could be used safely (just with additional care) in patient assessed to have a risk of substance abuse. The guide promoted the widespread use of opioids, stating that "[p]atients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient."

249. Additionally, the guide presented symptoms of genuine addiction as "pseudoaddiction" and taught doctors that the symptoms of addiction—such as demanding or manipulative behavior and obtaining opioid prescriptions from more than one physician—are actually pseudo-addiction, rather than addictive behavior that would necessitate the withdrawal of opioid treatment.

250. Upon information and belief, Purdue contributed funding to The American Academy of Pain Management ("AAPM"), a medical specialty society. AAPM issued a statement in 1997 that endorsed opioids and claimed that the risk of opioid addiction in people taking prescription opioids was low. The chairman of AAPM at that time was Dr. David Haddox. Dr.

Haddox was, at the time of the statement, a paid speaker for Purdue. He later went on to become Purdue's vice president for health policy.

251. In 2009 the American Pain Society ("APS") and AAPM jointly issued guidelines ("APS/AAPM Guidelines") recommending the use of opioids to treat chronic pain. The APS/AAPM guidelines promoted the use of opioids for the treatment of chronic pain and concluded that the risk of opioid addiction was manageable in patients regardless of previous histories of abuse. At least fourteen of the twenty-one panel members who drafted the APS/AAPM Guidelines received funding from Purdue.

252. The APS/AAPM Guidelines have been relied upon by doctors to inform their treatment of pain. They were cited repeatedly in academic literature and were even reprinted in the monthly medical journal, *Pain*. Upon information and belief, pharmaceutical sales representatives employed by Purdue discussed the APS/AAPM Guidelines with doctors during sales calls.

ii. Cephalon, Inc.

253. In 2008, the FDA found that Cephalon had promoted its fentanyl-containing lollipop, Actiq, for non-approved uses. Actiq had been "indicated" by the FDA for a specific use: to treat breakthrough pain in opioid-tolerant cancer patients who are already receiving around-the-clock opioid therapy. Cephalon, however, had been marketing Actiq for uses such as migraine headaches and other non-cancer pain, such as sickle-cell pain crises, and in anticipation of changing dressings or radiation therapy.

254. Cephalon also:

a) had sales representatives call on doctors who would not normally prescribe such drugs in the course of their practice;

b) trained sales representatives on techniques to prompt doctors into off-label conversations;

c) structured its employees' compensation and bonuses in a manner that encouraged off-label marketing;

d) had sales representatives instruct doctors how to get their patients' insurance to cover off-label uses;

e) use grants for continuing medical education to promote off-label uses; and

f) sent doctors to "consultant" meetings at lavish resorts to hear the company's off-label message.

255. As a result, Cephalon entered a plea agreement with the United States in which it admitted guilt to numerous violations of the FDCA and agreed to pay a record $425 million in penalties as part of a collective settlement related to the off-label market of multiple drugs, one including Actiq.

256. Cephalon was also required to:

a) send letters to doctors about the settlement agreement to enable doctors to report questionable sales representative conduct; and

b) post information about payments the manufacturer made to doctors on its website.

257. On March 26, 2009, Cephalon received a warning letter regarding its sponsored links on internet search engines (e.g. Google.com) for the opioid pain reliever Fentora, which made representations and/or suggestions about the efficacy of the said drug but failed to communicate any risk information.

258. The FDA found that the sponsored links omitted the most serious and frequently occurring risks associated with the Fentora, misleadingly suggesting Fentora is safer than demonstrated.

259. The FDA also found that the sponsored link for Fentora made incomplete and misleading statements about what the drug is indicated for, suggesting that Fentora is useful in a broader range of conditions or patients than had been demonstrated.

260. The FDA noted that the marketing material provided only a brief statement about what Fentora is indicated for, which was incomplete and misleading. Specifically, the marketing material suggested that Fentora is useful in a broader range of conditions or patients than is supported was by substantial evidence in clinical experience. The advertisement implied that Fentora was indicated for breakthrough pain in any patient with cancer, rather than only those who are already receiving, and already tolerant to, around-the-clock opioid therapy.

261. Additionally, the FDA found that the sponsored links did not present the full established name of said drug being promoted. Accordingly, the FDA found that the Cephalon's sponsored links misbranded Fentora in violation of the Federal Food, Drug, and Cosmetic Act and FDA implementing regulations. *See* 21 U.S.C. §§ 352(a) & (n), 321(n); 21 C.F.R. §§ 201.10(g)(1), 202.1(b)(1), (e)(3)(i), (ii) & (e)(6)(i).

262. On September 29, 2008, Cephalon pleaded guilty to 21 U.S.C. §§ 331(a), 331 (a)(1), and 352(f)(1) for marketing and promoting the opioids Actiq, for medical indications that were not approved by the FDA.

263. Between January 1, 2001 and December 31, 2006, Cephalon thus knowingly and willfully promoted the sale and use of Actiq for certain uses which the FDA had not approved (i.e. "unapproved uses").

264. The FDA approved Actiq, a fentanyl product manufactured as a lollipop, for use only in opioid-tolerant cancer patients (meaning those patients for whom morphine-based painkillers are no longer effective).

265. The drug is a strong and highly addictive narcotic, with significant potential for abuse. From 2001 through at least 2006, Cephalon was allegedly promoting the drug for non-cancer patients to use for such maladies as migraines, sickle-cell pain crises, injuries, and in anticipation of changing wound dressings or radiation therapy.

266. Cephalon promoted Actiq for use in patients who were not yet opioid-tolerant, and for whom it could have life-threatening complications and results.

267. Following its guilty plea, Cephalon pivoted to promoting Actiq through patient advocacy organizations or "Front Groups" posing as neutral and credible professional organizations in order to deliberately mislead the medical community and the general public while avoiding FDA violations. One such Front Group is the American Pain Foundation (APF).

268. At least fourteen of the twenty-one panel members who drafted the APS and AAPM Guidelines received funding from Cephalon. The guidelines recommended the use of opioids to treat chronic pain and concluded that the risk of opioid addiction was manageable in patients regardless of previous histories of abuse.

269. Cephalon provided considerable funding to FSMB, including $180,000 from 1997 through 2012. It also funded APF before withdrawing its support due to a Senate investigation.

iii. Janssen Pharmaceuticals, Inc.

270. On December 9, 1999, the FDA sent Janssen a letter indicating that it had reviewed a number of "homemade" marketing pieces that had been used by Janssen sales representatives for its fentanyl-based synthetic opioid, Duagesic. The FDA found those marketing pieces to be false

or misleading because they contained misrepresentations regarding safety information, broadened Duragesic's indication for use, contained unsubstantiated claims, and lacked fair balance.

271. FDA's warning letter provided the following examples of statements in the homemade marketing material that misrepresented safety information:

a) "Significantly LESS constipation!", which suggested Duragesic had been demonstrated to be associated with less constipation than other available opioids, thus, minimizing the risk of constipation; and

b) "Low abuse potential!", which suggested that Duragesic had less potential for abuse than other available opioids, and minimized and contradicted fentanyl's status as a Schedule II controlled substance.

272. FDA's warning letter provided the following example of a statement in the homemade marketing material that broadened Duragesiç's indication for use: "It's not just for end stage cancer anymore!" That suggested that Duragesic can be used for any type of pain management, and ignored the fact that Duragesic was indicated only for the management of chronic pain in patients who require continuous opioid analgesia for pain that cannot be managed by less powerful means. It also ignored the fact that use in persons other than those for whom Duragesic was indicated by FDA poses a high risk of death.

273. FDA's warning letter provided the following examples of unsubstantiated claims made in the homemade marketing material:

a) "Preferred regimen: 2 x per week versus 2 x per day!";

b) "Easy for Patient compliance."; and

c) "And the #1 reason to convert your patients to the Duragesic patch: QUALITY OF LIFE," and "… without pain, patient's [sic] sleep better, increase daily."

274. Janssen received further warning by way of a September 2, 2004 warning letter. That letter was in relation to Janssen's Duragesic patch. FDA found that a file card used by Janssen in connection with that patch contained false and misleading claims about the abuse potential of Duragesic, as well as unsubstantiated claims of the effectiveness of Duragesic. The FDA noted Janssen's representations could encourage the unsafe use of the drug, potentially resulting in serious or life-threatening hypoventilation, or even death.

275. The FDA requested a letter response (1) describing Janssen's intent to comply with FDA's requests, and (2) listing all promotional materials for Duragesic that were the same as or similar to the offending promotional materials. The FDA also requested that Janssen submit a plan for discontinuing use of the promotional marketing materials in question.

276. Janssen's promotional materials in question included:

a) "low reported rate of mentions in DAWN data" along with Drug Abuse Warning Network (DAWN) data comparing fentanyl/combination mentions to other listed opioid products, which suggested that Duragesic is less abused than other opioid drugs;

b) "minimizes the potential for local GI side effects by avoiding GI absorption," which suggested that Duragesic is associated with less constipation, nausea, and vomiting than oral opioids;

c) "demonstrated effectiveness in chronic back pain with additional patient benefits" which was based on an open-label, single arm trial with no control group which is clearly inadequate to support such a claim;

d) "86% of patients experienced overall benefit in a clinical study based on: pain control, disability in ADLs, quality of sleep", "all patients who

experienced overall benefit from Duragesic would recommend it to others with chronic low back pain", "significantly reduced nighttime awakenings" and "significant improvement in disability scores as measured by the Oswestry Disability Questionnaire and Pain Disability Index" which were again based on an open-label, single arm trial with no control group—which is inadequate to support such claims;

e) "Improved patient outcomes: Open-label, crossover comparison study", "Significant improvement in physical functioning summary score", and "Significant improvement in social functioning", which are based on an open label study lacking sufficient support for the cited claims; and

f) "1,360 loaves … and counting", "Work, uninterrupted", "Life, uninterrupted", "Game, uninterrupted", "Chronic pain relief that supports functionality", "Helps patients think less about their pain", and "Improvements in physical and social functioning" which imply that patients will experience improved social or physical functioning, a claim that Janssen lacks support for.

277. The FDA stated they were not aware of any substantial evidence or clinical experience to support these comparative claims.

278. On September 2, 2004 the FDA determined that Duragesic was misbranded and in violation of Section 502(a) of the Food, Drug, and Cosmetic Act. *See* 21 U.S.C. § 352(a).

279. Janssen thus made misleading safety claims and unsubstantiated effectiveness claims for Duragesic.

280. The FDA would not have approved Duragesic's label had Janssen disclosed misleading safety claims and unsubstantiated effectiveness claims for Duragesic at the time of the FDA approval process.

281. On August 26, 2011, Janssen received a warning letter regarding its opioid drug, Nucynta. The letter informed Janssen that the FDA had become aware of oral statements made by a Janssen representative that promoted an unapproved use for its opioid Nucynta, made unsubstantiated superiority claims about the drug, and minimized the serious risks associated with Nucynta.

282. The statements were made on December 8, 2010 at the 2010 American Society of Health-System Pharmacists ("ASHP") Midyear Clinical Meeting and Exhibition in Anaheim, CA.

283. The FDA requested a letter response that (1) described Janssen's intent to comply with the request, (2) listed all promotional materials for Nucynta that contained a violation resulting from that actions within the warning letter or similar to the actions in the warning letter, and (3) Janssen's plan for discontinuing use of such materials.

284. The Janssen representative promoted an unapproved use of Nucynta when the representative indicated that Nucynta is useful in the treatment of Diabetic Peripheral Neuropathic Pain ("DPNP"). Nucynta is not approved by the FDA for treatment of DPNP.

285. Janssen also made the following unsubstantiated superiority claims and statements that minimized the risk of Nucynta:

a) "DPNP patients stay on Nucynta for longer, and Nucynta provides 10 mg of opioid/oxycodone pain control, similar to Tramadol, but with less GI, constipation, nausea, and vomiting," which is misleading and implied that Nucynta is clinically superior compared to oxycodone and Tramadol for DPNP patients; and

b) When physicians prescribe Nucynta they "won't have to put patients on docusate or senna, patients get out of the hospital a day earlier which saves thousands of dollars because they are going to be able to have a bowel movement," which is misleading and implied that treatment with Nucynta has been shown to reduce the length of a hospital stay in comparison to oxycodone and Tramadol.

286. Following its FDA warnings, Janssen pivoted to promoting Duragesic and Nucynta through patient advocacy organizations or "Front Groups" posing as neutral and credible professional organizations in order to deliberately mislead the medical community and the general public while avoiding FDA violations. Such Front Groups included the APF, APS, and AAPM.

iv. Endo International PLC

287. On June 8, 2017 the FDA requested that Endo voluntarily remove from the market reformulated Opana ER—an opioid that was purportedly crush-resistant and thus supposedly decreased the risk of addiction. The FDA informed Endo that the benefits of Opana ER may no longer outweigh the risks.

288. Contrary to Endo's statements, reformulated Opana ER hardly reduced the risk of abuse. Instead, abuse of reformulated Opana ER by injection resulted in a serious disease outbreak of HIV and hepatitis C, as well as cases of thrombotic microangiopathy (a serious blood disorder).

289. Endo claimed to have reformulated Opana ER to be resistant for patients who crush and snort prescription opioid pills. Instead, the route of abuse significant shifted from insufflation (crushing and snorting) to intravenous injection.

290. The FDA released a statement confirming its decision was the first time the FDA had taken steps to remove a currently marketed opioid pain medication from sale due to public health concerns of abuse. The request, while voluntary, also stated that the FDA intended to take

steps to formally require its removal by withdrawing approval if Endo chose not to remove Opana ER.

291. Less than a month later, on July 6, 2017, Endo announced it would voluntarily remove Opana ER from the market after careful consideration and consultation with the FDA.

292. Endo was one of the primary contributors to the APF's numerous published guides and brochures for patients, doctors, and policymakers. The guides minimized the risks of addiction and exaggerated the benefits associated with prescription opioids, including but not limited to "Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families," sponsored by Endo, which falsely claimed that it is unlikely that people who are not predisposed to addiction will become addicted to opioid painkillers, and "Treatment Options: A Guide for People Living with Pain," which promoted opioids as essential for treating even "moderate" pain.

293. A June 8, 2012 letter submitted by FSMB to the Senate Finance Committee disclosed that Endo paid $50,000 respectively to fund the production of the "Responsible Opioid Prescribing," a guide authored by Dr. Scott Fishman, former chairman and president of the now defunct American Pain Foundation in 2007. The guide was ultimately disseminated to 700,000 practicing doctors. Since that time, Endo has paid the FSMB at least $371,620.

v. Actavis

294. On February 18, 2010, the FDA issued a warning letter to Actavis, the manufacturer of the opioid Kadian and one of the predecessor companies to Allergan, for distributing a false and misleading co-pay assistance brochure and comparison detailer.

295. The FDA's findings were based on Actavis' omissions and its minimization of serious risks associated with Kadian in its brochure; Actavis' failure to present the limitations to

Kadian's approved indication for use and its suggestions that it could be used for broader purposes than indicated; and its unsubstantiated claims of superiority and effectiveness.

296. The brochure presented several effectiveness claims regarding Kadian, but failed to present any contraindications and, additionally, omitted several warnings, precautions, drug interactions, and adverse events.

297. The brochure also failed to present risk information with a prominence and readability that is reasonably comparable to the presentation of benefit information.

298. The brochure also minimized the serious and significant risks associated with the use of Kadian by describing the serious and potentially fatal risks in highly complex, medically technical language not likely to be understood by consumers. The brochure simply included the following language, "Please see accompanying complete Prescribing Information" in an effort to mitigate the misleading omission and/or minimization of risk information.

299. In direct marketing to consumer marketing, Kadian's brochure included the following erroneous claims:

a) "Allow for less breakthrough pain and more consistent pain relief for patients";

b) "Better pain control …";

c) "Allow patients to live with less pain …";

d) "Allow individualization and customization of a patient's pain treatment";

e) "Prescribe KADIAN® - Less pain for your patients. More options for you."; and

f) "Less pain. More options."

300. The FDA informed Actavis that its brochure and detailer were false and misleading because they omitted and minimized the serious risks associated with Kadian, broadened and fail to present the limitations to the approved indication of Kadian, and presented unsubstantiated claims of superiority and effectiveness.

301. The FDA found Actavis' brochure and detailer for Kadian failed to include important and serious risk information including contraindications, adverse events, and warnings regarding potentially fatal abuse of opioids.

302. The FDA also found Actavis' brochure and detailer presented broad claims about Kadian's use in treating pain, therefore implying that Kadian was appropriate for use in a broader range of patients than the patients for which FDA approval was granted.

303. Finally, the FDA found Actavis' detailer included efficacy claims and presentations which were unsubstantiated, misleading and implied Kadian was superior to other opioid therapies. The FDA found Actavis' brochure and detailer misbranded the drug in violation of the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 352(a) & 321(n). Cf. 21 C.F.R. §§ 202.1(e)(3)(i); (e)(5); (e)(6)(i), (ii) & (xviii); (e)(7)(i) and (viii).

vi. Mallinckrodt

304. On March 30, 2009, Mallinckrodt received a letter from the FDA stating that Mallinckrodt was found to have been marketing an unapproved new drug, morphine sulfate concentrate oral solution 20 mg/ml, in violation of 21 U.S.C. §§ 331(d) and 355(a).

305. The letter also stated that its unapproved morphine formulation was misbranded under 21 U.S.C. § 352(f)(1) because the conditions it was intended to treat were not amenable to self-diagnosis and treatment. Adequate directions for such use, therefore, could not be written. As

a result, introduction or delivery for introduction into interstate commerce of its unapproved morphine formulation violated 21 U.S.C. §§ 331(a) and (d).

306. Mallinckrodt had been marketing its unapproved morphine formulation since 2005.

307. Mallinckrodt provided considerable funding to FSMB including at least $100,000.

308. Separately and together, Manufacturer Defendants thus engaged in a sustained misinformation campaign regarding both (1) the safety and efficacy of opioids generally; and (2) their products in particular. That misinformation campaign, propagated at times through industry-funded Front Groups, paid tremendous dividends. Across the country, including in the State of Maine, doctors began prescribing powerful opioids for a wide range of ailments. In turn, patients became addicted—setting into motion the raging opioid epidemic plaguing America today.

VI. Defendants' Duties Under the Federal Controlled Substances Act and Regulations and the Maine Pharmacy Act and Board of Pharmacy Regulations

309. The opioid supply chain begins with the Manufacturer Defendants, who manufacture and package the pills. The Manufacturer Defendants then transfer the opioids to wholesale distributors, including the Distributor Defendants.[61] The Distributor Defendants then dispense the opioids to hospitals and pharmacies. Those entities (which include Retailer Defendants) then dispense drugs to patients.

310. Each of the Defendants herein breached common law duties as well as statutory obligations under federal and state law.

A. Federal Controlled Substances Act and Regulations

311. In 1970 Congress enacted the Controlled Substances Act (CSA), 21 U.S.C. § 801 *et seq.*, to establish a framework under which the federal government regulates certain drugs

[61] Collectively, Distributor Defendants account for over 90% of all drugs distributed within the United States.

which, although they have legitimate medical and scientific uses, nevertheless carry a high risk of illegal diversion for illegal and harmful purposes.[62]

312. The CSA places various plants, drugs, and chemicals (such as narcotics, stimulants, depressants, hallucinogens, and anabolic steroids) into one of five schedules based on the substance's medical use, potential for abuse, and safety or dependence liability.[63]

313. Schedule I lists the most dangerous substances (e.g., heroin). These have no medical use and have a high potential for abuse. Schedule II drugs (e.g., methadone, morphine, oxycodone (OxyContin) have a currently accepted medical use but also have a high potential for abuse which may lead to severe psychological or physical dependence.[64] Virtually all the prescriptions opioids herein are regulated as Schedule II controlled substances.

314. In addition, the Act requires persons who handle controlled substances or listed chemicals (such as drug manufacturers, wholesale distributors, doctors, hospitals, pharmacies, and scientific researchers) to register with the Drug Enforcement Administration (DEA) in the U.S. Department of Justice, which administers and enforces the CSA.[65] All the Defendants in this matter therefore were and are required to register with the DEA. See 21 U.S.C. § 823(a)-(b); 21 C.F.R § 0.100.

315. The CSA sets forth two relevant controls on hazardous drugs. *First*, the DEA sets limits on the quantity of schedule II-controlled substances—such as opioids—that may be produced in the United States in any given year. *See* 21 U.S.C. § 826(a). 28 C.F.R. § 0.100. DEA

[62] Bryan T. Leh, Cong. Res. Service, *The Controlled Substances Act: Regulatory Requirements, Summary* (December 3, 2012).
[63] *Id*, at p. 1.
[64] *Id*. See also, p. 16.
[65] *Id.*

determines these quotas based on a variety of data including sales, production, inventories, and exports. The DEA can and does lower quotas as a means of addressing abuse and diversion.

316. *Second*, Defendants, as registrants, must maintain detailed records of their respective controlled substance inventories as well as establish adequate security controls to minimize theft and diversion.[66] Defendants herein therefore were and are required to "maintain . . . effective controls against diversion" and to "design and operate a system to disclose . . . suspicious orders of controlled substances." 21 U.S.C. § 823(a)-(b); 21 C.F.R § 1301.74.

317. In requiring registrants to design systems to control diversion, Congress anticipated that highly addictive prescription drugs like opioids could be abused and diverted to the black market. The CSA thus sought to combat diversion of prescription narcotics by providing for a closed system of drug distribution in which every actor in the opioid supply chain—*i.e.*, manufacturers, wholesale distributors, and retailers—must register with the DEA. Every registrant, in turn, is charged with being vigilant in deciding whether a customer, pharmacy, wholesaler, or end customer, can be trusted to deliver or use controlled prescription narcotics only for lawful purposes. 21 U.S.C. 823(e). Specifically, every registrant—manufacturers, wholesale distributors, and retailers—is required to "maintain effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. § 823(b)(1).

318. Therefore, the CSA and its implementing regulations require all registrants to (1) report suspicious orders of prescription opioids to the DEA, and (2) perform required due diligence prior to filling any suspicious orders. *See* 21 U.S.C. § 823(b)(1); 21 C.F.R. § 1301.74(b). A

[66] *Id.*

"suspicious order" is defined as including "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. §1301.74(b).

319. In addition, the Code of Federal Regulations (CFR) requires all registrants—manufacturers, wholesale distributors, and retailers—to "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21. C.F.R. §1301.74(b). Therefore, in addition to reporting suspicious orders, a registrant, whether a manufacturer, wholesaler or retailer, must exercise due diligence in confirming the legitimacy of all orders prior to filling.

320. The requirements imposed on Defendants by the CSA and the applicable regulations—including the requirements to report suspicious orders, and to create a system to disclose suspicious orders—are crucial. As the United States Supreme Court has explained, the CSA was Congress's attempt "to conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." *Gonzales v. Raich*, 545 U.S. 1, 12 (2005).

321. "Congress," the Court has explained, "was particularly concerned with the diversion of drugs from legitimate channels. It was aware that registrants, who have the greatest access to controlled substances and therefore the greatest opportunity for diversion, were responsible for a large part of the illegal drug traffic." *United States v. Moore*, 423 U.S. 122, 135 (1975).

322. Manufacturers, distributors and retailers therefore must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.

323. Reflecting the importance of CSA compliance, the DEA has repeatedly provided guidance to registrants emphasizing their obligations under the CSA. A DEA letter dated September 27, 2006, sent to every commercial entity in the United States registered with the DEA, outlined specific circumstances that might be indicative of diversion:

a) Ordering excessive quantities of a limited variety of controlled substances while ordering few if any other drugs.

b) Ordering a Limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered.

c) Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs.

d) Ordering the same controlled substance from multiple distributors.

324. Additionally, the letter implored Distributor Defendants to know their pharmacy customers, including Retailer Defendants, and to follow-up with said pharmacy customers, including Retailer Defendants, regarding:

a) What percentage of the pharmacy's business does dispensing controlled substances constitute?

b) Is the pharmacy complying with the laws of every state in which it is dispensing controlled substances?

c) Is the pharmacy soliciting buyers of controlled substances via the internet or is the pharmacy associated with an internet site that solicits orders for controlled substances?

d) Does the Pharmacy, or Internet site affiliated with the pharmacy, offer to facilitate the acquisition of a prescription for a controlled substance from a practitioner with whom the buyer has no pre-existing relationship?

e) Does the pharmacy fill prescriptions issued by practitioners based solely on an on-line questionnaire without a medical examination or bona-fide doctor-patient relationship?

f) Are the prescribing practitioners licensed to practice medicine in the jurisdictions to which the controlled substances are being shipped, if such a license is required by state law?

g) Are one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy?

h) Does the pharmacy offer to sell controlled substances without a prescription?

i) Does the pharmacy charge reasonable prices for controlled substances?

j) Does the pharmacy accept insurance payment for purchases of controlled substances made via the internet?

325. In 2007, the DEA sent letters to every registered manufacturer or distributor of controlled substances, including Defendants. As stated in the letter, "the purpose of [the] letter [wa]s to reiterate the responsibilities of controlled substance manufacturers and distributors to inform the DEA of suspicious orders in accordance with 21 C.F.R. § 1301.74(b)."

326. In the letter, the DEA expressly warned that the regulation "requires that the registrant inform the local DEA Division Office of suspicious orders when discovered by the registrant." The DEA also warned that "[r]egistrants are reminded that their responsibility does not end merely with the filing of a suspicious order report. Registrants must conduct an

independent analysis of suspicious orders prior to completing a sale to determine whether the controlled substances are likely to be diverted from legitimate channels. Reporting an order as suspicious will not absolve the registrant of responsibility if the registrant knew, or should have known, that the controlled substances were being diverted."

327. In addition, the DEA warned that the "regulation specifically states that suspicious orders include orders of an unusual size, orders deviating substantially from a normal pattern, and orders of an unusual frequency. These criteria are disjunctive and are not all inclusive. For example, if an order deviates substantially from a normal pattern, the size of the order does not matter and the order should be reported as suspicious. Likewise, a registrant need not wait for a 'normal pattern' to develop over time before determining whether a particular order is suspicious. The size of an order alone, whether it deviates from a normal pattern, is enough to trigger the registrant's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the order patterns of the particular customer, but also on the patterns of the registrant's customer base and the patterns throughout the relevant segment of the regulated industry."

328. The federal CSA also imposes a duty upon each Defendant herein to comply with applicable State and local laws. *See* 21 U.S.C.A. § 823(b)(2).

B. Maine Pharmacy Act and Board of Pharmacy Regulations

329. In addition to the federal CSA, Defendants herein are also required to comply with Maine state law and regulations.

330. Maine state law explicitly incorporates the FDCA and CSA and its applicable regulations, along with other federal laws and regulations, by way of the regulations of the Maine

Pharmacy Act, 32 MSRA §13701 *et seq*. and its accompanying regulations. See Maine Board of Pharmacy. See 02-392 CMR Pt. 5, Ch. 29, §1 (1, 2), §2.

331. The laws and rules incorporated by the regulations of the Maine Board of Pharmacy including the FDCA, the CSA, and other federal laws, establish standards of professional conduct applicable to all the defendants herein. 02-392 CMR Pt. 5, Ch. 29, §§1-2.

332. Unprofessional conduct includes, but is not limited to, any violation of, among other laws, the FDCA and the CSA, as they relate to prescription drugs and controlled substances. 02-392 CMR Pt. 5, Ch. 29, §§1-2.

333. Further, extensive regulations pertaining to the operation of retail pharmacies are set forth by the regulations of the Maine Board of Pharmacy at 02-392 CMR Pt. 3, Ch. 13. See also 02-392 CMR Pt. 5, Ch. 30, §1 (1-13).

334. Extensive regulations pertaining to the operations of wholesalers and manufacturers are set forth by the regulations of the Maine Board of Pharmacy at 02-392 CMR Pt. 3, Ch. 16, §2 (8, 10). See also 02-392 CMR Pt. 5, Ch. 30, §1 (1-13).

335. Standards of professional behavior are further enumerated in the regulations of the Maine Board of Pharmacy at 02-392 CMR Pt. 5, Ch. 30, §1 (1-13).

336. Pursuant to the Maine Pharmacy Act, 32 MRSA §13742-A(1)(C), any violations of the laws and rules incorporated by the Maine Board of Pharmacy regulations constitutes unprofessional conduct and, in addition to other grounds, may lead to denial of licensing, refusal to renew a license, or the imposition of disciplinary sanctions.

337. Under the regulations of the Maine Board of Pharmacy, "'wholesale distribution' is the distribution of prescription drugs by wholesale distributors to persons other than consumers or patients . . ." subject to enumerated exceptions inapplicable here. 02-392 CMR Pt. 1, Ch. 1 (36).

338. Further, a "[w]holesale distributor is anyone engaged in wholesale distribution of prescription drugs, including, but not limited to manufacturers . . ." 02-392 CMR Pt. 1, Ch. 1 (37). The Manufacturer and Distributor Defendants, the Retailer Defendants, therefore are "wholesale distributors" within the meaning of the regulations of the Maine Board of Pharmacy.

339. Under Maine law, wholesale distributors are required to comply with the provisions of the CSA, 21 U.S.C. §801 *et seq.*, and the regulations set forth in 21 CFR Parts 1300-1301, and 1304-14.

340. Retail pharmacists under the regulations of the Maine Board of Pharmacy are "responsible legally and professionally for all activities related to the practice of pharmacy within the retail pharmacy for which the licensee is registered as pharmacist in charge, and for the pharmacy's compliance with the provisions of the Maine Pharmacy Act, the rules of the board, and the federal laws and rules specified in Chapter 29, Section 1 of the board's rules." 02-392 CMR Pt. 5, Ch. 13, §3 (2).

341. Retail pharmacists, pursuant to 02-392 CMR Pt. 5, Ch. 29, §1, are obligated to conform their conduct to various federal statutes, including the Drug Abuse and Prevention Control law, including but not limited to the CSA, 21 U.S.C §801 *et seq.*, and its applicable regulations, 21 CFR Parts 1300-1301, 1302, 1304-14.

342. Maine retail pharmacists further are obligated to provide effective controls and guard against theft and diversion of controlled substances, pursuant to 32 MSRA §13742-A(1)(C) and the regulations pertaining to the Maine Board of Pharmacy. See 02-392 CMR Pt. 5, Ch. 29, §1 (2).

343. Each of the Defendants herein owed the Passamaquoddy Tribe–Pleasant Point statutory duties under the regulations of the CSA, and as incorporated under the regulations of the

Maine Board of Pharmacy, including the duty to "provide effective controls and procedures to guard against theft and diversion of controlled substances." See 21 C.F.R. § 1301.71(a); 02-392 CMR Pt. 5, Ch. 29, §§1-2; 02-392 CMR Pt. 5, Ch. 30, §1 (1-13).

344. Likewise, under the Maine pharmacy regulations, each of the Defendants herein therefore owed the Passamaquoddy Tribe–Pleasant Point statutory duties under the regulations of the Maine Board of Pharmacy under which they pharmacists are obligated to "establish controls against diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels." See 02-392 CMR Pt. 5, Ch. 30, §1 (13).

VII. Defendants' Failures to Maintain Effective Controls Against Diversion and Failures to Report Suspicious Orders

345. In addition to their misleading marketing**,** the opioid epidemic was further fueled by all the Defendants' failure to follow the specific mandates in the CSA and Maine state laws and regulations requiring them to ensure that highly addictive drugs are not diverted to illegal use. The brunt of the opioid epidemic could have been, and should have been, prevented had the Defendants fulfilled their duties set by statute and common law. The Defendants, who operate at every level of the opioid supply chain, had an obligation and duty to act. They did not—and the country, including the Passamaquoddy Tribe–Pleasant Point—paid the price.

346. On information and belief, the Defendants knowingly, recklessly, and/or negligently supplied suspicious and excessive quantities of prescription opioids to obviously suspicious physicians and pharmacies in and around the reservation and tribal lands of the Passamaquoddy Tribe–Pleasant Point, without disclosing suspicious orders as required by regulations and otherwise circumventing their statutory obligations under Federal and Maine state law.

347. The Defendants' refusal to report and investigate suspicious orders had far-reaching effects. As mentioned above, the DEA is required to annually set production quotas for regulated drugs. In the context of opioids, however, DEA has cited the difficulty of determining an appropriate production level to ensuring that adequate quantities are available for legitimate medical use. That is because there are no direct measures available to establish legitimate medical need. DEA's difficulty in setting production quotas was compounded by the fact that the Manufacturer, Distributor, and Retailer Defendants failed to report suspicious orders of opioids—and failed to maintain effective controls against diversion. The Defendants' deliberate failures thus prevented the DEA from realizing the full extent of opioid diversion for years.

348. Defendants could have (and should have) reported and stopped the flow of prescription opioids into the black market. But Defendants intentionally, recklessly, and/or negligently failed to investigate, report, and halt suspicious orders. Accordingly, as a direct result of Defendants' misconduct, substantial and dangerous quantities of prescription opioids were illegally diverted to and overprescribed in the Passamaquoddy Tribe–Pleasant Point reservation.

A. Failure of the Manufacturer Defendants

349. Manufacturers are the source of the prescription drugs in the pharmaceutical supply chain. The pharmaceutical manufacturing industry is composed of two distinct business models: manufacturers of brand-name drugs and manufacturers of generic drugs.

350. Manufacturers manage the actual distribution of drugs from manufacturing facilities to drug wholesalers, and in some cases, directly to retail pharmacy chains, mail-order and specialty pharmacies, hospital chains, and some health plans. Manufacturers may also distribute products directly to government purchasers, such as the Veterans Administration.

351. Upon information and belief, Manufacturer Defendants collected, tracked, and monitored extensive data concerning suspicious physicians and pharmacies through third-party organizations and through defendant distributors and defendant pharmacies in exchange for rebates or other consideration to better drive sales.

352. For example, IMS Health (now named IQVIA) furnished Purdue and other Manufacturer Defendants with fine grained information about the prescribing habits of individual doctors and the ordering habits of individual pharmacies.

353. Manufacturer Defendants could have used this data to identify diversion as required under federal law, to satisfy its duty of ""effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." *See* 21 U.S.C. § 823(b)(1).

354. Instead, they utilized the data to understand which regions, and which doctors, to target through their sales force.

355. With the knowledge that Retailer Defendants and prescribing doctors were facilitating diversion, Manufacturer Defendants failed to report each instance of diversion to the DEA while rolling out marketing campaigns to churn its prescription opioid sales.

356. Indeed, upon information and belief, the Manufacturer Defendants withheld from the DEA information about suspicious orders—and induced the Distributor Defendants and the Retailer Defendants to do the same—to obfuscate and conceal the extent of the opioid epidemic. Upon information and belief, the Manufacturing Defendants knew that if they or the other defendants disclosed suspicious orders, the DEA would become aware that many opioids were being diverted to illegal channels and would refuse to increase the production quotas for opioids.

357. Upon information and belief, at least Purdue referred to overprescribing doctors or doctors engaged in diversion as "whales."[67]

B. Failure of the Distributor Defendants

358. The Distributor Defendants purchase prescription opioids from the Manufacturer Defendants to distribute to a variety of customers, including Retailer Defendants (retail and mail-order), hospitals, long-term care, and other medical facilities (e.g., community clinics, physician offices and diagnostic laboratories).

359. The top three wholesale distributors, McKesson, Cardinal Health, and AmerisourceBergen, account for almost 90 percent of the entire wholesale drug market. This consolidation has forced the industry to change its revenue model, evolving its core distribution business into a low-margin enterprise that makes money by maximizing economies of scale, i.e. the more opioids they distribute the lower their margins.

360. Distributor Defendants utilize "just-in-time" delivery methods. In order to keep inventory and liability of pharmaceutical drugs as low as possible, most pharmacies receive drug deliveries from distributors every day of the week. This allows the pharmacy to hold as little inventory of pharmaceutical drugs on site as possible. In making just-in-time deliveries, sometimes multiple times a day to a single pharmacy, distributors know precisely how many opioid prescriptions and individual pills they are delivering to a specific pharmacy.

361. On information and belief, Distributor Defendants supplied Manufacturer Defendants with distribution data in exchange for rebates or other consideration so Manufacturer Defendants could better drive sales.

[67] Evan Hughes, *The Opioid that Made a Fortune for Its Maker—and for Its* Prescribers, New York Times (May 2, 2018).

362. Distributor Defendants report the sale of all prescription opioids, including those to Retailer Defendants in State of Maine, to the Automation of Reports and Consolidated Orders System ("ARCOS") database. The ARCOS database's purpose is to monitor the flow of DEA controlled substances from their point of manufacture through commercial distribution channels but does not include prescription or doctor data.

363. The ARCOS database does not alert the DEA to the suspicious nature of a particular order. The DEA investigators regard the database as unwieldy because it encompassed dozens of drugs sold by more than a thousand companies and is frequently six months out of date.

364. Distributors are a crucial link in the closed system envisioned by Congress in enacting the CSA. Wholesale distributors are the closest link to pharmacies in the pharmaceutical supply chain, as such, they are best situated to determine whether a pharmacy is facilitating the diversion of prescription opioid pills.

365. Industry compliance guidelines established by the Healthcare Distribution Management Association, the trade association of pharmaceutical distributors, explain that distributors, including Distributor Defendants, are "[a]t the center of a sophisticated supply chain" and, therefore, "are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers."

366. Distributor Defendants are a key link in the pharmaceutical supply chain, as they that have the power to determine that an order is not being diverted before filling suspicious orders—thereby preventing diversion before it can even occur.

367. Reporting an order as suspicious will not absolve a distributor, including Distributor Defendants, of responsibility if the registrant and distributor knew, or should have known, that the prescription opioids were being diverted. Indeed, reporting a suspicious order,

then filling said order with knowledge it may be suspicious constitutes a failure to maintain effective controls against diversion under 21 U.S.C. §§ 823 and 824, requiring Defendants to operate in compliance with applicable state laws and regulations.

368. Once the DEA started to enforce suspensions of registrations to distribute controlled substances, rather than comply, manufacturers and defendants spent at least $102 million to undermine the DEA's ability to do so.

369. On February 19, 2014, acting at the behest of industry lobbyists, Representative Tom Marino introduced the "Ensuring Patient Access and Effective Drug Enforcement Act" as a supposed effort to define "imminent danger" in the 1970 act. A DEA memo noted that this bill would essentially destroy the agency's power to file an immediate suspension order of any suspicious drug shipments.

370. This bill required that the DEA show the company's actions had shown "substantial likelihood of an immediate threat," whether in death, serious bodily harm or drug abuse before a suspension order can be sought. It also gave drug companies the ability to submit "corrective action" plans before any penalties could be issued. The law essentially makes it impossible for the DEA to halt any suspicious narcotic shipments before opioids are diverted to the illegal black market.

i. The Distributor Defendants Failed to Track and Report Suspicious Sales as Required by Maine and Federal Law

371. The following fines reflect only a small portion of the hundreds of billions of dollars in revenue the Distributor Defendants receive each year.

a. McKesson

372. McKesson is a significant distributor of opioids in the United States and is currently under investigation by a coalition of 41 State Attorneys General, including Maine Attorney General Janet T. Mills, regarding its distribution of opioid products.

373. In or about 2007, the DEA accused McKesson of failing to report suspicious orders and launched an investigation. In 2008, McKesson entered into a settlement agreement with the DOJ and a memorandum of agreement, agreeing to pay a $13.25 million fine for failure to report suspicious orders of pharmaceutical drugs and promising to set up a monitoring system.

374. As a result, McKesson developed a Controlled Substance Monitoring Program ("CSMP") but nevertheless failed to design and implement an effective system to detect and report "suspicious orders" for controlled substances distributed to its independent and small chain pharmacy customers – *i.e.*, orders that are unusual in their frequency, size or other patterns. McKesson continued to fail to detect and disclose suspicious orders of controlled substances. It failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers and bypassed suspicious order reporting procedures set forth in the CSMP.

375. Despite the CSMP, a DEA investigation revealed that between 2008 and 2013, McKesson continued to fail to inform the DEA about a plethora of suspicious orders of prescription opioids. In that time period, a single warehouse in Aurora, Colorado filled 1.6 million prescription orders and reported only 16 as suspicious.

376. As recently as December 17, 2017 facts continue to emerge regarding McKesson's misdeeds. According to both the Washington Post Article and "60 Minutes," McKesson's failures from 2008 to 2013 were so egregious that members of the DEA believed that it warranted a

criminal case against the drug distribution company. Apparently, members of the DEA thought prison sentences for McKesson executives would be warranted.

377. The DEA's Denver field division, in conjunction with a local law enforcement investigation into the Platte Valley Pharmacy in Brighton, Colorado, ascertained that the vast majority of pills prescribed at the Platte Valley Pharmacy originated at McKesson's warehouse in Aurora, Colorado. According to local law enforcement, a single pharmacist, Jeffrey Clawson, was selling as many as 2,000 opioids a day.

378. None of the 16 suspicious orders that McKesson actually reported from 2008 to 2013 were related to the Platte Valley Pharmacy, or to Jeffrey Clawson.

379. This was in spite of the fact that, from 2008-2011, the percentage increase for oxycodone 30 mg orders supplied by McKesson to Platte Valley Pharmacy was approximately 1,469%. Jeffrey Clawson was eventually indicted and convicted of drug trafficking charges and was given a 15 year prison sentence.

380. McKesson eventually did report Jeffrey Clawson's suspicious orders, but only after he had already been convicted and the Platte Valley Pharmacy closed and was no longer a source of revenue.

381. Upon information and belief, Distributor Defendants had a policy of not reporting suspicious orders until the DEA was already aware of wrongdoing. In this way the Distributor Defendants believed they could protect themselves from liability, while obfuscating the true extent of opioid diversion to keep DEA quota on opioids high.

382. Prior to Jeffrey Clawson's indictment, McKesson did not report, as suspicious, that a small pharmacy in rural Colorado needed the more prescription opioids than a medical center in

the city of Denver. Nor did it report a more than fourteen-fold increase in prescription opioids deliveries to Platte Valley Pharmacy over only three years was out of place.

383. The DEA's Denver field division rightly realized that if McKesson had been so bold in Colorado, it likely was ignoring suspicious orders elsewhere. What surprised the DEA most was that McKesson would be so reckless in spite of its violations in 2007 and the implementation of the CSMP program.

384. Subsequently, nine field divisions of the DEA working with 12 U.S. attorney's offices across 11 states began to collect information on McKesson's activity.

385. What they found was striking. McKesson hadn't just been ignoring suspicious orders. Rather, McKesson was acutely aware of the situation at Platte Valley Pharmacy. Worse, McKesson warehouses in Livonia (a suburb of Detroit, Michigan), and in Washington Court House, Ohio were supplying pharmacies that sold to criminal drug rings. In all, 12 McKesson distribution centers, failed to report suspicious orders involving millions of opioids across the country. The DEA even pushed to completely revoke McKesson's Livonia location's registration to distribute controlled substances.

386. The DEA investigative finding revealed that McKesson systematically:

a) Supplied controlled substances in support of criminal diversion activities;

b) Ignored blatant diversion;

c) Would arbitrarily increase the threshold amount of opioids pharmacies could purchase;

d) Failed to review orders for suspicious activity; and

e) Ignored own procedures designed to prevent diversion.

387. David Schiller of the DEA's Denver field division, which first recognized McKesson's bad acts, asserted that "This is the best case we've ever had against a major distributor in the history of the Drug Enforcement Administration." Individuals at the DEA believed that a fine of more than $1 billion would be appropriate, and one unnamed source asserted that "[the DEA] could have fined them out of existence, or indicted the company and put [McKesson, the 5th largest Corporation in the United States] out of business.

388. It was only after the DEA visited the Aurora, Colorado location on March 2013 that McKesson started to comply, enhancing its monitoring program that resulted in report of 2,447 suspicious orders between June and November of that year.

389. On January 17, 2017, McKesson agreed to pay a record $150 million in fines and suspend sales of controlled substances from distribution centers in four states (Colorado, Ohio, Michigan and Florida) to settle allegations that the company violated federal law As part of the agreement, McKesson acknowledged that: "at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA." The company promised to institute significant changes to its program designed to flag suspicious orders, the same promise it made and broke in 2008.

390. McKesson was fined the equivalent of less than two year's salary of its board chairman and chief executive, John Hammergren.

391. The DEA agents who were involved in the investigation believed that McKesson escaped criminal liability because McKesson had "intimidated" the lawyers of the chief counsel's office in the Division of Diversion Control.

b. Cardinal Health

392. Cardinal Health is a significant distributor of opioids in the United States and is currently under investigation by a coalition of 41 State Attorneys General, including Maine Attorney General Janet T. Mills, regarding its distribution of opioid products

393. Cardinal fully acknowledged that from January 1, 2009 to May 14, 2012 it did fail to comply with regulations that required reports of any suspicious orders from pharmacies. Cardinal Health's chief legal and compliance officer, Craig Morford, also noted that going forward it would work "with all participants in addressing the epidemic of prescription drug abuse." In a press release from Cardinal Health on January 9, 2017, Cardinal Health notes that it is continuously improving a "sophisticated anti-diversion program that includes advanced analytics, technology, and the deployment of teams of anti-diversion specialists and investigators embedded within its supply chain," to address suspicious orders that are likely meant for illegitimate use.

394. On December 23, 2016, Cardinal Health agreed to pay the United States $44 million to resolve allegations that it violated the Controlled Substances Act in Maryland, Florida and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA.

395. In the settlement agreement, Cardinal Health admitted, accepted and acknowledged that it had violated the CSA between January 1, 2009 and May 14, 2012 by failing to:

a) "timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b)";

b) "maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required

by 21 C.F.R. §1301.74, including the failure to make records and reports required by the CSA or DEA's regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5)"; and

c) "execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA 'Form 222' order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. § 828 and 21 C.F.R. Part 1305."

396. In the press release announcing the settlement agreement, U.S Attorney for the District of Maryland, Rod Rosenstein, stated: "Pharmaceutical suppliers violate the law when they fill unusually large or frequent orders for controlled substances without notifying the DEA … Abuse of pharmaceutical drugs is one of the top federal law enforcement priorities. Cases such as this one, as well as our $8 million settlement with CVS in February 2016, reflect the federal commitment to prevent the diversion of pharmaceutical drugs for illegal purposes."

397. In the press release, DEA's Washington Division Special Agent-in-Charge, Karl Colder, clarified that the settlement specifically concerned oxycodone: "[The] DEA is responsible for ensuring that all controlled substance transactions take place within DEA's regulatory closed system. All legitimate handlers of controlled substances must maintain strict accounting for all distributions and Cardinal failed to adhere to this policy … Oxycodone is a very addictive drug and failure to report suspicious orders of oxycodone is a serious matter. The civil penalty levied against Cardinal should send a strong message that all handlers of controlled substances must perform due diligence to ensure the public safety …"

c. AmerisourceBergen

398. AmerisourceBergen is a wholesale distributor of pharmaceuticals, including controlled substances and non-controlled prescription medications. It handles the distribution of

approximately 20% of all pharmaceuticals sold and distributed in the U.S. through a network of 26 pharmaceutical distribution centers.

399. AmerisourceBergen is a significant distributor of opioids in the United States and is currently under investigation by a coalition of 41 State Attorneys General, including Maine Attorney General Janet T. Mills, regarding its distribution of opioid products.

400. In 2012, West Virginia sued AmerisourceBergen and Cardinal Health, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws and the creation of a public nuisance. Unsealed court records from that case demonstrate that AmerisourceBergen, along with McKesson and Cardinal Health, together shipped 423 million pain pills to West Virginia between 2007 and 2012. AmerisourceBergen itself shipped 80.3 million hydrocodone pills and 38.4 oxycodone pills during that time period. Moreover, public documents also demonstrate that that the average dose of each tablet distributed grew substantially during that time period. The Distributor Defendants, including AmerisourceBergen, shipped large quantities of oxycodone and hydrocodone tablets to the state. In 2016, AmerisourceBergen agreed to settle the West Virginia lawsuit by paying $16 million to the state, with the funds set aside to fund drug treatment programs in order to respond to the opioid addiction crisis.

d. Mallinckrodt PLC

401. On July 11, 2017, Manufacturer Defendant Mallinckrodt PLC agreed to pay $35 million to the United States Department of Justice ("DOJ") to settle charges stemming from violations of certain provisions of the Controlled Substances Act, such as (1) 21 C.F.R. 1301.74(b) for failing to design and operate a system to disclose to the registrant suspicious orders of controlled substances and to inform the DEA Field Division office of such suspicious orders when

discovered, (2) 21 C.F.R. 1301.71(a) for failing to provide effective controls and procedures to guard against theft and diversion of controlled substance.

402. The July 2017 agreement by Mallinckrodt PLC also settled charges by the DOJ stemming from Mallinckrodt PLC's failure to utilize chargeback data received from distributors to identify suspicious orders of customers further down in the supply chain, such as order from pharmacies or pain clinics from distributors, which Mallinckrodt required distributors provide it with in order to obtain chargeback discounts.

403. Finally, the agreement settled charges stemming from allegations by the DOJ that Mallinckrodt PLC was guilty of record-keeping violations at its manufacturing facility in upstate New York, which created discrepancies between the actual number of oxycodone tablets manufactured in a batch and the number of tablets Mallinckrodt PLC reported on its records.

e. Omnicare

404. As a result of a multi-jurisdictional investigation by the DOJ, CVS' subsidiary OmniCare, Inc., the nation's leading provider of pharmaceutical care for seniors, was fined $50 million for violations of the Controlled Substances Act.

405. According to the investigation, from 2007 to 2012, OmniCare Inc., filled out prescriptions without requiring signed prescriptions by a prescribing doctor. Rather, OmniCare Inc. would dispense prescription narcotics upon oral orders from long term care facility staff. In other words, OmniCare Inc. regularly dispensed opioids without a prescription without knowing who they were dispensing opioids to.

f. Masters

406. Masters has a long history of noncompliance with DEA standards. The DEA has, on two separate occasions, issued orders to show cause why Masters' DEA certificate of

registration should not be revoked. On October 17, 2008 the DEA issued an order that alleged that throughout 2007 and 2008, Masters "failed to maintain effective controls against diversion" of hydrocodone. Masters agreed to settle charges brought by the DEA on April 1, 2009.

407. Masters paid $500,000 and agreed to take steps to bring the company into compliance with DEA regulations for detecting suspicious orders and preventing diversion of controlled substances. However, on August 9, 2013 the DEA again issued an order to show cause why Masters' certificate of registration should not be revoked.

408. The 2013 order alleged that Masters ignored and/or failed to implement its controlled substance policies and failed to report suspicious orders.

409. Evidence raised during trial showed that Masters did not report orders held as potentially suspicious, even going so far as to, on numerous occasions, delete orders to they would no longer trigger the hold. Even when customers provided information which confirmed that an order was indeed suspicious, Masters still failed to report the orders to the DEA.

410. On September 8, 2015 Chuck Rosenberg, Acting Administrator of the DEA ordered Masters' DEA certificate of registration be revoked. On June 30, 2017 the United States Court of Appeals for the District of Columbia Circuit denied Masters' petition for review.

C. Failure of the Retailer Defendants

411. Pharmacies are the final step on the pharmaceutical supply chain before drugs reach the consumer/patient. Pharmacies purchase drugs from wholesalers, and occasionally directly from manufacturers, and then take physical possession of the drug products.

412. Since they are the final point of sale for pharmaceuticals and the interface between the supply chain and the consumer, pharmacies generate the data that manufacturers as well as wholesale distributors rely upon to measure consumer activity for sales purposes.

413. Pharmacies have the most accurate data on individual doctors' prescribing habits. On information and belief, Retailer Defendants provided Manufacturer Defendants with data regarding individual doctors in exchange for rebates, or other form of consideration.

414. Most pharmacies purchase their drug supply from a wholesale distributor, although some retailers are large institutional and retail chain pharmacies that obtain drugs directly from a manufacturer. These organizations can deal directly with manufacturers because they already possess the operational infrastructure necessary to bypass wholesalers – warehousing facilities, distribution vehicles, and inventory control systems. Once a pharmacy takes possession of the drug products, it distributes the products to physicians or directly to consumers.

i. Duties of Retail Pharmacies

415. Pharmacists are the last line of defense in keeping drugs from entering the illicit market. They are meant to be the drug experts in the healthcare delivery system and as such have considerable duties and responsibility in the oversight of patient care. They cannot blindly fill prescriptions written by a doctor, even one registered under the CSA to dispense opioids, if the prescription is not for a legitimate medical purpose. Pharmacists are the gatekeepers of a closed system of prescription drug distribution designed to protect the health, safety and welfare of our citizens through limited access to drugs that can have serious and lethal adverse consequences.

416. The CSA requires pharmacists to review each controlled substance prescription and, prior to dispensing medication, make a professional determination that the prescription is for a legitimate medical purpose.

417. Under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of controlled substances." 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. 1306.04(a) states, "The responsibility for the proper prescribing

and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." *See* 21 C.F.R. § 1306.04(a).

418. Further, the DEA's 2010 "Practitioner's Manual" section on "Valid Prescription Requirements" instructs that "an order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription." Filling such a prescription is illegal. The manual states: "The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted."

419. As noted hereinabove, under the applicable Maine state laws and regulations, pharmacists are "responsible legally and professionally for all activities related to the practice of pharmacy within the retail pharmacy for which the licensee is registered as pharmacist in charge, and for the pharmacy's compliance with the provisions of the Maine Pharmacy Act, the rules of the board, and the federal laws and rules specified in Chapter 29, Section 1 of the board's rules." See 02-392 CMR Pt. 5, Ch. 13, §3 (2).

420. Pharmacists therefore, pursuant to 02-392 CMR Pt. 5, Ch. 29, §1, are obligated to conform their conduct to various federal statutes, including the Drug Abuse and Prevention Control law, including but not limited to the CSA, 21 U.S.C §801 *et seq.*, and its applicable regulations, 21 CFR Parts 1300-1301, 1302, 1304-14.

421. Maine Pharmacists are further obligated under the regulations pertaining to the Maine Board of Pharmacy to provide effective controls and guard against theft and diversion of controlled substances. See 02-392 CMR Pt. 5, Ch. 29, §1 (2).

422. Specifically, Maine pharmacists, as well as the other Defendants herein, are obligated to "establish controls against diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels." See 02-392 CMR Pt. 5, Ch. 30, §1 (13).

ii. Retail Pharmacy Defendants' Policy of Speed over Accuracy Was Negligent

423. The Retail Defendants adopted several policies including performance metrics and quotas. CVS, for example, calls this policy The Metrics System.

424. The performance metric system rates the Retailer Defendants' stores pharmacist employees based solely on productivity. These requirements placed significant and unrealistic time pressures on pharmacists.

425. Retailers measure how many and how quickly prescriptions are filled daily based on store volume. Upon information and belief, many Retailer Defendants' locations require pharmacists to fill one prescription every three minutes. The program also measures how many telephone calls are made to customers to refill and/or pick up prescriptions; how many flu shots are given; as well as other pharmacy tasks. All measurements focus on productivity with the end goal of maximizing retail defendants' profits.

426. Under CVS's Metrics system, for example, pharmacists are directed to meet unobtainable goals. If they met those goals, they would violate the law regarding their professional responsibilities and governing practice rules.

427. There is no measurement for pharmacy accuracy or customer safety.

428. Due to the Metrics and other similar system, pharmacists cannot meet their directives and are forced to decide whether they violate the law and regulations pharmacists must comply with, or attempt to meet the company directives.

429. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions pharmacists can fill within a year.

430. Upon information and belief, Retailer Defendants required their employee pharmacists to fill more than 600 prescriptions per work shift.

431. The MAPS system debuted in 2003 and was not substantially upgraded until 2016. Upon information and belief, a query to MAPS can take as long as fifteen minutes.

432. While Retailer Defendants increased demands for productivity, they cut the hours for pharmacy technicians, leaving pharmacists severely understaffed and unable to provide all services required by the MAPS system.

433. To satisfy the increased productivity demands with decreased staffing required pharmacists employed by Retailer Defendants to cut corners in their performance of due diligence obligations implemented through the MAPS system and, consequently, violate their legal obligations as it relates to their professional responsibilities and governing practice rules under Maine and federal law.

434. Retailer Defendants' high-volume-and-increased-profits business model also led to a greater number of errors in dispensing prescriptions, which can result in significant harm to pharmacy customers.

435. A survey conducted by the Institute for Safe Medication Practices. ("ISMP") of 673 pharmacists revealed that 83% believed that distractions due to performance metrics or measured wait times contributed to dispensing errors, and that 49% felt specific time measurements were a significant contributing factor.

436. Further, the National Association of Boards of Pharmacy found that performance metrics, which measure the speed and efficiency of prescription work flow—using such

parameters as prescription wait times, percentage of prescriptions filled within a specified time period, number of prescriptions verified, and number of immunizations given per pharmacist shift—may distract pharmacists and impair professional judgment.

437. The practice of applying performance metrics or quotas to pharmacists in the practice of pharmacy may cause distractions that could potentially decrease pharmacists' ability to perform drug utilization review, interact with patients, and maintain attention to detail, which could ultimately lead to unsafe conditions in a pharmacy.

438. Multiple studies show that the more prescription drugs a pharmacist is required to dispense the more likely that pharmacists will make dispensing errors. Including the following:

a) B.G. Guernsey, N.B. lngrim, J.A. Hokanson, W.H. Doutre, S.G. Bryant, C.W. Blair & E. Galvan, *Pharmacists' dispensing accuracy in a high-volume outpatient pharmacy service: focus on risk management*, 17 Annals of Pharmacotherapy 742–46. (1983) (“There was a trend for the number of pharmacist-hours containing at least one potentially serious dispensing error to increase as the prescription-filling rate accelerated. Outpatient pharmacies with high volumes should set a limit to the number of prescriptions filled by their pharmacists and should experiment with quality assurance systems to reduce dispensing errors and subsequent legal liabilities.”)

b) K.L. James, D. Barlow, R. McArtney, S. Hiom, D. Roberts & C. Whittlesea, C. *Incidence, type and causes of dispensing errors: a review of the literature*, 17 Int’l J. Pharm Practice 9-30 (2009) (“High workload, interruptions, distractions and inadequate lighting were objectively shown to increase the occurrence of dispensing errors.")

c) E. Schafheutle, *Factors influencing pharmacist performance: a review of the peer-reviewed literature*, 102 Health Policy 178–92 (2011) ("Factors relating to workload and work environment were associated with performance problems, particularly in relation to errors.")

439. The Retailer Defendants' productivity policies are directly at odds with their performance of due diligence obligations required to be performed in conjunction with the MAPS system. Indeed, their policies financially disincentive their pharmacists from exercising due diligence under Maine and federal law, especially given the higher duty of care associated with the prescription of narcotic opioids, and create an untenable situation ripe for diversion.

440. The Retailer Defendants failed to adequately train their pharmacists and pharmacy techs on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal.

441. The Retailer Defendants failed to instruct their pharmacists and pharmacy techs on how to address situations in which they are forced to decline filling a prescription for a customer who submitted a prescription which a pharmacist has identified as suspicious.

442. The Retailer Defendants have failed to train their pharmacists and pharmacy techs on how to properly exercise their judgment and intuition with respect to determinations about whether a prescription is one that should be filled, or whether, under the law, the pharmacist should refuse to fill it.

443. The Retailer Defendants failed to adequately use data available to them to identify doctors that were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids.

444. The Retailer Defendants failed to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that contributed to the opioid crisis. Upon information and belief, the Retailer Defendants failed to analyze:

a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community;

b) the increase in opioid sales relative to past years;

c) the number opioid prescriptions filled relative to other drugs; and

d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

445. The Retailer Defendants failed to conduct internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly.

446. The Retailer Defendants failed to have trained personnel monitoring media and journal publications regarding issues with all drugs being sold, including opioids.

447. The Retailer Defendants failed to heed communications from government agencies, to the public and to Retailer Defendants specifically, and take action.

448. The Retailer Defendants failed to effectively respond to concerns from raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

449. The Retailer Defendants' own sales representatives, agents, employees, contractors, and other persons who rendered services in furtherance of selling more of the Retailer Defendants' drugs, upon information and belief, raised a significant number of complaints, statements of concern, and observations of regarding suspicious prescriptions, which the Retailer Defendants failed to investigate, act upon, and in some cases even acknowledge or create records of.

450. Upon information and belief, the Retailer Defendants knew, reasonably should have known, or, if they did not know, intentionally remained willfully blind to the fact of the media and journal attention published about the opioid epidemic. They intentionally remained willfully blind to the fact that pill diversion and pill mills were increasing at an alarming rate. And, upon information and belief, the Retailer Defendants failed to act.

451. The Retailer Defendants failed to track or observe increase in antidote sales, which would have triggered suspicion in a reasonable person or a reasonable sales representative that levels of prescription drug abuse were rampant.

452. The Retailer Defendants failed to observe, take notice of, and take into account, government communications to the public and to those involved in the opioid supply chain, such as the Retailer Defendants, and take action.

453. The Retailer Defendants failed to track profit changes for opioids, which skyrocketed once the epidemic was truly underway and would have signaled to any reasonable person, pharmacist, or executive that a crisis involving narcotic drugs was underway.

454. The Retailer Defendants in fact knew of massive sales and negotiated purchase contracts more favorable to them, which in turn created further pressure on sales representatives.

455. The Retailer Defendants knew that supply procedures had to change to address the ever increasing volume of drugs being sold—which was so patently obvious that it required an update to a larger physical storage space for the volume of pills being moved.

456. The Retailer Defendants intentionally, maliciously, and repeatedly failed to investigate or act upon complaints, statements of concern and observations of employees.

457. The Retailer Defendants clearly knew that an opioid epidemic existed as that they considered and/or implemented changes to their security procedures to address retail outlet concerns regarding customers who were, may have been, or had the potential to become addicts.

iii. Retail Pharmacy Defendants and/or their Subsidiaries or Franchisees Failed to Track and Report Suspicious Sales as Required by Maine and Federal Law

458. The Retailer Defendants were subject to multiple DEA investigations regarding their failure to meet their obligations under the CSA as DEA registrants.

a. CVS

459. In 2013, CVS Pharmacy, Inc. paid $11,000,000 in fines for violations of the CSA. According to the DEA press release:

460. "The United States has alleged that from October 6, 2005 to October 5, 2011, CVS pharmacy retail stores violated the CSA and the record-keeping regulations by";

a) Creating, entering and maintaining invalid "dummy" DEA registration numbers or numbers other than the valid DEA registration number of the prescribing practitioner on dispensing records, which were at times provided to state prescription drug monitoring programs;

b) Filling prescriptions for certain prescribers whose DEA registration numbers were not current or valid; and

c) Entering and maintaining CVS dispensing records, including prescription vial labels, in which the DEA registration numbers of non-prescribing practitioners were substituted for the DEA registration numbers of the prescribing practitioners."

461. CVS has knowledge and/or notice of the opioid problem since at least 2002.

462. At any time since CVS had knowledge and/or notice of the opioid problem it could have unilaterally taken steps to curtail and prevent expansion of the problem, but it failed to do so.

463. Rather than act to curb the expansion of opioid use that CVS knew was occurring at a breathtaking pace, CVS chose not to undertake and/or failed to take action to induce internal consideration of any of the measures it was capable of taking.

464. In addition to measures alleged above, CVS could and should have unilaterally taken action, and/or offered a program to third-party payers, which had the effect of:

a) Limiting to seven days the supply of opioids dispensed for certain acute prescriptions;

b) Reducing the dispensing of stronger and extended release opioids;

c) Enhancing pharmacist counseling for new opioid patients;

d) Limiting the daily dosage of opioids dispensed based on the strength of the opioid; and

e) Requiring the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

465. CVS could have and should have implemented these measures at any point in the last 15 years.

466. CVS considered some of these measures prior to June 2017 but chose not to act on their implementation until September 2017.

467. Having knowledge and/or notice of the damages that CVS conduct had caused to Plaintiff and others, CVS failed to take other steps to help curb the damages already incurred by Plaintiff. Such step CVS could have included, among other things:

a) Donating medication disposal units to community police departments across the country to ensure unused opioid painkillers are disposed of properly rather than taken by individuals to whom the prescription was not written or otherwise diverted or abused;

b) Implementing a program that consists of providing counseling to patients who are receiving an opioid prescription for the first time, such as by discussing the risks of dependence and addiction associated with opioid use and discussing and answering any questions or concerns such patients may have; and

c) Running a public education campaigns in which CVS Pharmacists' Teach Program share facts about opioid abuse with students and parents.

b. Rite Aid

468. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid Corporation ("Rite Aid") and nine of its subsidiaries in eight states were fined $5 million in civil penalties for its violations of the Controlled Substances Act ("CSA").

469. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and federal regulations that lead to the diversion of prescription opioids in and around the communities of the Rite Aid pharmacies investigated and Rite Aid failed to notify the DEA of losses of controlled substances in violation of 21 USC 842(a)(5) and 21 C.F.R 1301.76(b).

470. In an effort to preserve good will, Rite Aid, in partnership with Albertsons announced in February 2017 that it was expanding access to naloxone, the opioid antagonist drug that is extremely effective at reversing the effects of an opioid overdose and saving the lives of those affected.

471. In addition to measures alleged above, Rite Aid could and should have unilaterally taken action that and/or offered a program to third-party payers to accept that:

a) Limited to seven days the supply of opioids dispensed for certain acute prescriptions;

b) Reduced the dispensing of stronger and extended release opioids;

c) Enhanced pharmacist counseling for new opioid patients;

d) Limited the daily dosage of opioids dispensed based on the strength of the opioid; and

e) Required the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

472. Having knowledge and/or notice of the damages that Rite Aid conduct had caused to Plaintiff and others, Rite Aid failed to take other steps to help curb the damages already incurred by Plaintiff due to Defendants, including Rite Aid, could have:

a) Donated medication disposal units to community police departments across the country to ensure unused opioid painkillers are disposed of properly rather than taken by individuals to whom the prescription was not written or otherwise diverted or abused;

b) Implemented a program that consists of providing counseling to patients who are receiving an opioid prescription for the first time, such as by discussing the risks of

dependence and addiction associated with opioid use and discussing and answering any questions or concerns such patients may have; and

c) Run public education campaigns in which Rite Aids ran public education programs.

d) Limited to seven days the supply of opioids dispensed for certain acute prescriptions;

e) Reduced the dispensing of stronger and extended release opioids;

f) Enhanced pharmacist counseling for new opioid patients;

g) Limited the daily dosage of opioids dispensed based on the strength of the opioid; and

h) Required the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

473. Rite Aid could have and should have implemented these measures at any point in the last 15 years.

474. And the failure to take such steps that Rite Aid should have taken was negligent and did result in significant damages to Plaintiff.

c. Walgreens

475. In 2013, as a result of a multi-jurisdictional investigation by the DOJ, Walgreens Corporation was fined $80 million for its violations of the CSA.

476. According to the investigation Walgreens committed an unprecedented number of record-keeping and dispensing violations under the CSA. According to documents filed in the underlying administrative actions, Walgreens negligently allowed controlled substances listed in Schedules II – V of the Act, such as oxycodone and other prescription pain killers, to be diverted for abuse and illegal black market sales.

477. On September 20, 2017, Walgreens announce that the pharmacy was launching its #ItEndsWithUs campaign to educate teens about the opioid epidemic. As part of that initiative, the company created a website that serves as an online "#ItEndsWithUs" hub and resource center aimed at disseminating the risks of opioid abuse, guides on how to properly dispose of unused opioids, and even testimonials from individuals who personally overcame opioid addictions.

478. Additionally, the #ItEndsWithUs" hub provides the locations of free-to-use medication-disposal kiosks where individuals can deposit their unused medication into a safe-box, the contents of which will be later disposed of in a safe and proper manner.

479. In the wake of a recent $500,000 fine, Walgreens adopted a "good faith dispensing" policy that allows a pharmacist to refuse to dispense pain relievers if the pharmacist feels that the prescriber failed to write a prescription for a legitimate medical purpose.

480. In a letter issued to prescribing physicians, Walgreens stated: "According to 21 C.F.R. 1306.04, pharmacists are required to ensure that prescriptions for controlled substances are issued for a legitimate medical purpose." The precise text of the regulation to which Walgreens' letter referred, in pertinent part, is as follows:

> The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

481. Walgreens also took additional steps to combat the opioid crisis, although such efforts were admittedly late in the game including launching a safe medication disposal program in which the company installed drug disposal kiosks in more than 500 Walgreens drugstores in 39

states and Washington D.C., as well as eliminating the requirement persons present a prescription before being permitted to obtain the life-saving medication, Naloxone (in 35 states including Washington, D.C.). When a patient receives naloxone, Walgreens provides mandatory counseling on the risks of opioids, risk factors for and how to avoid overdose, how to identify and respond to an overdose, and how to use and administer Naloxone.

482. In addition to measures alleged above, Walgreens could and should have unilaterally taken action that and/or offered a program to third-party payers to accept that:

a) Limited to seven days the supply of opioids dispensed for certain acute prescriptions;

b) Reduced the dispensing of stronger and extended release opioids;

c) Enhanced pharmacist counseling for new opioid patients;

d) Limited the daily dosage of opioids dispensed based on the strength of the opioid; and

e) Required the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

483. Having knowledge and/or notice of the damages that Walgreens conduct had caused to Plaintiff and others, Walgreens failed to take other steps to help curb the damages already incurred by Plaintiff due to Defendants, including Walgreens, could have:

a) Donated medication disposal units to community police departments across the country to ensure unused opioid painkillers are disposed of properly rather than taken by individuals to whom the prescription was not written or otherwise diverted or abused;

b) Implemented a program that consists of providing counseling to patients who are receiving an opioid prescription for the first time, such as by discussing the risks of dependence and addiction associated with opioid use and discussing and answering any questions or concerns such patients may have;

c) Run public education campaigns in which Walgreens ran public education programs;

d) Limited to seven days the supply of opioids dispensed for certain acute prescriptions;

e) Reduced the dispensing of stronger and extended release opioids;

f) Enhanced pharmacist counseling for new opioid patients;

g) Limited the daily dosage of opioids dispensed based on the strength of the opioid; and

h) Required the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

484. Walgreens could have and should have implemented these measures at any point in the last 15 years.

485. And the failure to take such steps that Walgreens should have taken was negligent and did result in significant damages to Plaintiff.

d. Walmart

486. Defendant Walmart also was subject to DEA investigations and paid penalties and fines for violations of the CSA.

487. For example, in 2009, Walmart paid a $637,000 fine to resolve allegations brought by the U.S. Attorney regarding numerous record-keeping violations at Walmart pharmacies in

Texas. The allegations included that Walmart had failed to provide invoices for controlled substances and timely file records indicating loss or theft of drugs to the DEA, in violation of the Comprehensive Drug Abuse Prevention and Control Act.[68]

488. Each of the Retailer Defendants had knowledge and/or notice of the damages caused and continuing to be caused by their conduct and could and should have taken measures, including but not limited to those set forth herein, to curb opioid expansion of opioid use and to prevent or minimize the cascading damages caused by their wrongful conduct.

VIII. Examples of Unreported Suspicious Prescribing Habits or Orders in Maine

489. Maine, like many others states, has experienced numerous instances of opioid over-prescription, diversions and thefts by licensed physicians, as well as by licensed Maine pharmacists, interns, and technicians.

490. For example, Joel Sabean, MD, of Portland, ME, was found guilty by a federal jury on November 18, 2016, in U.S. District Court, District of Maine, of 52 counts Unlawful Distribution of Controlled Substances, five counts Tax Evasion, and one count Health Care Fraud.

491. According to court documents, Sabean was a Dermatologist practicing in Portland, Maine. Between December, 2010 and January, 2014, Sabean knowingly and willfully wrote prescriptions and dispensed Controlled Substances to a family member not for a legitimate medical purpose and outside the course of professional practice. For tax years 2008-2012, Sabean filed over $3,000,000 in fraudulent medical deductions.

492. From 2013-September 2015, 372 complaint cases regarding illegal drug diversions, including mostly opioids, were opened under the Maine Pharmacy Act. These complaints resulted in numerous license revocations of pharmacists, interns, and technicians.

[68] *See Walmart fined for Pharmacy Record-Keeping Violations*, Ozarks First, Jan. 7, 2009, http://www.ozarksfirst.com/news/health-and-medical/walmart-fined-for-pharmacy-record-keeping-violations

IX. The Statutes of Limitations are Tolled by Defendants' Fraudulent Concealment and Fraud and They are also Estopped from Relying upon Statutes of Limitations as a Defense

A. The Statutes of Limitations Are Tolled by Defendants' Fraudulent Concealment and Fraud

493. Pursuant to 14 Maine Revised Statutes (M.R.S.) §859: "If a person, liable to any action mentioned, fraudulently conceals the cause thereof from the person entitled thereto, or if a fraud is committed which entitles any person to an action, the action may be commenced at any time within 6 years after the person entitled thereto discovers that he has just cause of action.. . ." 14 M.R.S. §859.

494. The running of any statute of limitations applicable to this matter has been tolled pursuant to 14 M.R.S. §859 by the Defendants' efforts to deceive the Plaintiff and to fraudulently conceal their unlawful conduct by fraudulently assuring the Plaintiff and the public that they were complying with their obligations under federal and state laws pertaining to controlled substances. This fraudulent concealment was purposely undertaken by the Defendants in order to protect their status as registrants under state and federal controlled substances laws and to continue to generate corporate profits from the sales and distribution of opioid products.

495. Defendants purposely and deliberately undertook actions to conceal their fraudulent and conspiratorial conduct in deceptively marketing opioid products and their role in promoting and creating the oversupply of opioids which inevitably resulted in overprescribing, suspicious sales, diversions, and of opioids and thereby caused the present opioid epidemic in communities across the United States, including that of the Plaintiff.

496. The running of any statute of limitations has also been tolled pursuant to 14 M.R.S. §859 by the Manufacturing and Distributor Defendants' fraudulent marketing scheme and by their

fraudulent concealment from governmental entities, the medical profession, the public, and the Plaintiff of the risks to the health and safety of the consumers of their opioid products.

497. These Defendants conspired in a fraudulent marketing scheme to promote the use of opioids for the management of pain which they knew to be medically inappropriate and which they knew would result in misuse, addiction, overdose, and diversion of their opioid products. Their fraudulent marketing scheme was intended to mislead, and did in fact mislead, physicians, patients, health care providers, health care payors, governmental entities, and Plaintiff that Defendants' opioid products were safe and effective for treatment of chronic, non-cancer pain.

498. These Defendants' marketing campaign fraudulently concealed the dangers of their opioid products by promoting numerous falsehoods regarding the safety and efficacy of their opioid products to governmental entities, the medical profession and the public. Defendants fraudulently concealed that opioids, when used as directed, were, among other things, not effective for daily, long-term treatment of non-cancer pain, carried a high risk of abuse and diversion, and were addictive.

499. These Defendants actively undertook and conspired in a fraudulent scheme to deceptively promote opioids and to deceive and induce the medical profession to increase prescriptions of their opioid products to patients through the use of monetary incentives, subsidized payments, gifts, and bribes to physicians, industry funded front groups, and through misleading and untruthful publications and advertising, among other unscrupulous marketing practices.

500. These Defendants also fraudulently concealed the existence of Plaintiff's and other's legal claims by manipulating and distorting public information, knowledge, and facts; and by negligently and recklessly failing to make public or otherwise produce nonpublic information, over which they had exclusive possession, dominion, and control, such as reports that those treated

with opioids in clinical trials exhibited behaviors which revealed that the opioids were addictive; data showing that large amounts of opioids were being diverted from legitimate, legal channels and used inappropriately for medical treatment; and information that specific doctors and pharmacies were engaged in an illegal pattern of conduct that was designed to provide, in exchange for monies, opioids to persons who did not suffer from FDA approved indications.

501. For example, the Manufacturer Defendants fraudulently concealed from Plaintiff the existence of Plaintiff's claims by deliberately concealing information about conduct they knew to be illegal by other members of the opioid supply chain. In addition, one Manufacturer Defendant deployed a team of representatives to push prescribers to recommend dosing no more frequently than every 12 hours, despite affirmative knowledge that such prescribing practices were ineffective and increased patients' propensity to become addicted. Further, the Manufacturer Defendants sponsored organizations that falsely represented themselves experts and advocates for patients regarding the treatment of pain while simultaneously promoting a fraudulent marketing scheme regarding the safety and effectiveness of their prescription opioid products.

502. Further, the statutes of limitations are tolled under 14 M.R.S. §859 because all the Defendants fraudulently concealed from the government their knowledge regarding suspicious orders and other diversions of their opioid products. The statutes are also tolled by the Defendants' fraudulent concealment of their failure to meet their obligations under federal and state law to report suspicious orders of opioid products and by their failure to establish and maintain effective controls against diversion of prescription opioid products into illicit channels and markets.

503. The Defendants fraudulently concealed from Plaintiff the existence of Plaintiff's claims by misrepresenting their compliance with their legal duties under state and federal law and

by wrongfully and repeatedly disavowing those duties in an effort to mislead regulators and the public regarding the Distributor Defendants' compliance with their legal duties.

504. The Distributor Defendants, for example, fraudulently concealed the existence of Plaintiff's claims by affirmatively seeking to convince the public that their legal duties had been satisfied through public assurances that they were working to curb the opioid epidemic. Cardinal Health, through an executive, claimed that it used "advanced analytics" to monitor the supply chain and falsely represented that it was being "as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity." McKesson stated that it has a "best-in-class controlled substance monitoring program to help identify suspicious orders" and claims that it is "deeply passionate about curbing the opioid epidemic in our country."

505. Given each Distributor Defendants' sales volumes and history of violations, these false statements were made intentionally and fraudulently or recklessly without regard to the truth and as a positive assertion.

506. The Distributor Defendants also fraudulently concealed the existence of Plaintiff's claims through wrongful and repeated disavowal of their duties under state and federal law by individually and collectively through trade groups in the industry pressuring the U.S. Department of Justice to "halt" prosecutions and lobbying Congress to strip the DEA of its ability to immediately suspend distributor registrations.

507. As a result of their efforts, the Distributor Defendants caused a sharp drop in enforcement actions and secured the passage of legislation raising the legal hurdle the DEA must clear before revoking a registrant's license, an act which was entitled ironically the "Ensuring Patient Access and Effective Drug Enforcement Act."

508. This fraudulent concealment was intended to increase the sales of and profits from their opioid products, and did so successfully, by preventing the government and the public from controlling or restricting the Defendants marketing, sales, and distribution of their opioid products through the enforcement of regulatory actions and controls and to preclude Plaintiff and others from taking any legal action to redress the opioid crisis and recover their damages proximately caused by Defendants' misconduct and fraudulent concealment.

509. These Defendants also fraudulently concealed from governmental entities, including the Plaintiff, as well as the medical profession and the public, the increased costs and burden on governmental services and productivity which they knew would be inflicted by opioid-related misuse, addiction, overdose, and diversion, among other negative impacts.

510. Plaintiff was unaware of the underlying truth about the Defendants' opioids. Plaintiff reasonably or justifiably relied on those misrepresentations to its detriment because the Defendants possessed and controlled more information about their opioids than any other party and such reliance was harmful to Plaintiff as set forth in the damages section of this Complaint.

B. Defendants Are Equitably Estopped from Relying Upon the Statutes of Limitations

511. The Defendants are equitably estopped under Maine law from relying upon the statutes of limitations as a defense to Plaintiff's claims because they conducted and knowingly participated in, and conspired in, a fraudulent marketing campaign and opioid supply chain which was based upon false representations, as described herein, regarding the addictiveness and efficacy of their prescription opioid products. This fraudulent marketing campaign was calculated to mislead government agencies, the medical profession, the public and the Plaintiff and to induce Plaintiff to forgo legal action.

512. Furthermore, the Manufacturer and Distributor Defendants are equitably estopped from relying on any statute of limitations as a defense to any of Plaintiff's claims because they undertook affirmative actions to prevent Plaintiff from discovering the existence of its claims in a timely fashion. These Defendants were under a duty to disclose the true character, quality, and nature of their opioid products, which was nonpublic information over which these Defendants had and continue to have exclusive possession, dominion, and control. However, these Defendants breached their duty by failing to disclose such information and by intentionally and fraudulently concealing these facts.

513. In addition, all the Defendants are estopped because they made material misrepresentations about the existence of, and their compliance with, their duties with respect to distributing controlled substances under state and federal law. These statements were false, and the Defendants were aware of their falsity, because the Defendants were aware of their own history of conduct which included repeated breaches of such duties;

514. The Defendants are also equitably estopped under Maine law because they committed numerous acts of negligence which are the equivalent of fraud. They are estopped because they breached their duty to Plaintiff to comply with federal and state laws, as described herein, which required them to implement a system to report suspicious orders of opioids and to maintain effective control against diversion of opioid products. Such breaches are equivalent to fraud because they were based on numerous false representations directed at government regulators and agencies, the medical profession, the public, and the Plaintiff regarding the safety and effectiveness of their opioid products.

515. Furthermore, during the relevant time, the Defendants derived massive profits from their marketing, sales and distribution of prescription opioids. The Defendants expended

enormous sums of money to further their fraudulent purpose of marketing and promoting a profitable opioid drug by misrepresenting its safety and efficacy. Plaintiff Passamaquoddy Tribe–Pleasant Point, on the other hand, lacked the economic and resources, as well as the requisite expertise, to investigate or determine the nature, extent and identity of the health and other risks related to Defendants' opioid products. As a result, the public, including Plaintiff, were forced to rely on Defendant's fraudulent representations.

516. Defendants' breaches of their duties as registrants under the federal CSA and the Maine Pharmacy Act and Board of Pharmacy laws and regulations to report and prevent suspicious orders of opioids, and to implement a system to maintain control against the diversion of controlled opioid products, was the proximate cause of all the damages asserted by Plaintiffs.

517. Additionally, the Distributor Defendants are estopped from relying on a statute of limitations as a defense to any of Plaintiff's claims because each such Defendant took affirmative action to prevent plaintiffs such as the Passamaquoddy Tribe–Pleasant Point from discovering the existence of and filing its claims in a timely fashion.

518. Plaintiff had no knowledge that the Defendants were engaged in any of the fraud and wrongdoing alleged herein. Because of the fraudulent acts of concealment and wrongdoing by the Defendants, as well as their failures to meet their obligations under the CSA and Maine Pharmacy Act and Board of Pharmacy laws and regulations, the Plaintiff could not have reasonably discovered the wrongdoing at any time prior.

519. Plaintiff Passamaquoddy Tribe–Pleasant Point did not know the representations made by Defendants regarding the safety and efficacy of their opioid products were false. The Defendants intended that members of the public, including Plaintiff, to rely upon such representations. Plaintiff therefore reasonably relied on Defendants' misrepresentations and

fraudulent concealment to its detriment, as demonstrated by the damages suffered by Plaintiff as set forth herein.

520. Plaintiff Passamaquoddy Tribe–Pleasant Point could not have afforded, and did not have the requisite expertise, to investigate adequately to determine the nature, extent and identity of the health and other risks associated with Defendants' opioid products. The Defendants had the economic and other resources, and did spend vast sums of money in furtherance of their purpose of marketing and promoting a profitable drug despite their knowledge of , notwithstanding the known or reasonably known risks. The Defendants all derived massive profits as a result of their sales and distribution of prescription opioids. As a result, the public and members thereof, including Plaintiff, were forced to rely on Defendant's untrue and fraudulent representations.

C. Continuing Tort

521. Defendants' misconduct, fraudulent misrepresentations, and fraudulent concealment have been comprised of a series of events or chain of conduct extending over a continuous period of time.

522. The harms which Plaintiff has suffered as a proximate result of Defendants' misconduct, fraudulent misrepresentations, and fraudulent concealment are continuing in nature and have not terminated.

523. Plaintiff is therefore entitled to relief from the running of the statutes of limitations because the wrongdoing and unlawful activities of the Defendants' have not ceased and the damages caused to the Plaintiff have not abated.

X. Exemplary Damages

524. Plaintiff Passamaquoddy Tribe–Pleasant Point incorporates herein by reference all the foregoing allegations and further alleges as follows.

525. Defendants' conduct was outrageous, extremely dangerous, exceeded reckless disregard, and was malicious thereby entitling Plaintiff to an award of exemplary or punitive damages.

526. Defendants were manufacturing, marketing, selling, and distributing massive quantities of highly dangerous, highly regulated prescription drugs which are statutorily categorized as posing a high potential for abuse, addiction, and diversion.

527. Defendants were legally required to register under the federal law which regulates opioids as dangerous controlled substances. 21 CSA § 801 *et seq*. Under the CSA and its accompanying regulations, as well as under other federal and state laws, Defendants were legally required, among numerous other regulatory obligations, (a) to be truthful and forthcoming regarding all the risks to human health associated with their prescription drug product, (b) to be truthful regarding the safety and efficacy of their products, (c) to keep accurate and complete records of all transactions involving their opioid products, (d) to report suspicious orders or diversions of their products, and (e) to establish and maintain effective controls against diversion of their prescription opioid products into illicit channels.

528. Defendants were and are subject to severe civil and criminal penalties, fines, and sanctions for failure to meet their obligations under the extensive federal and state regulatory scheme which applies to controlled substances such as prescription opioid drug products.

529. Defendants were aware of the vast medical, scientific, and historical evidence regarding the well-known risks and harms associated with misuse, addiction, and diversion of opioids into illicit channels.

530. Nevertheless, despite their extensive legal and regulatory obligations, and despite their knowledge of the dangerous risks associated with their prescription opioid products, the

Defendants knowingly and maliciously conspired amongst themselves to design and promote a fraudulent marketing campaign which was intended to mislead government agencies, the medical professions, the public, and others regarding the safety and efficacy of their opioid product for the treatment of chronic non-cancer pain.

531. Further, the Defendants, in furtherance of their fraudulent scheme, went to great lengths and expended vast sums to deceive and influence government regulators, the medical profession, and the public regarding the safety and efficacy of their opioid product. Defendants pursued this outrageous and fraudulent strategy through the use of unscrupulous and deceitful marketing practices, set forth herein, including (a) the funding of phony front organizations induced to mispresent the safety and efficacy of their product, (b) the bribing of physicians to prescribe their opioid products, (c) the publication of untruthful articles in professional medical journals, (d) the payment of speaking fees to physicians and opinion leaders to misrepresent their product, and the corruption of physicians with fees falsely characterized as speaking fees when no speeches were given, among numerous other unscrupulous and fraudulent actions.

532. Defendants persisted in these fraudulent schemes despite (a) numerous warnings from the FDA regarding their misleading promotions of their opioid products; (b) numerous enforcement actions, fines and warnings from the U.S. Department of Health and Human Services and the Department of Justice, (c) paying massive sums to settle civil and criminal penalties, and agreeing to extensive and detailed corporate integrity agreements, (d) pleading guilty to federal charges of misbranding their opioid products, and (e) having numerous show cause orders and immediate suspension being issued against them by the DEA for failure to maintain effective controls against diversion of their opioid products, among other civil and criminal proceedings and actions.

533. Defendants maliciously conspired and implemented this fraudulent marketing scheme and supply chain for their dangerous and ineffective products while flouting their legal obligations solely to generate massive profits.

534. Defendants' outrageous and malicious conduct has resulted in thousands of addictions, overdoses, and deaths of American citizens and has imposed massive societal costs and an economic burden on government agencies, communities, and groups, including the Plaintiff Passamaquoddy Tribe–Pleasant Point. The most recent analysis has estimated that Defendants outrageous misconduct has imposed a staggering cost of *$78.5 billion per year*, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.[69]

535. Defendants' conduct was malicious, outrageous, and extremely dangerous conduct, for which the imposition of exemplary damages would undeniably serve the purposes of deterrence and punishment, or both.

536. Plaintiff Passamaquoddy Tribe–Pleasant Point therefore seeks an award of exemplary or punitive damages against the Defendants herein.

CAUSES OF ACTION

COUNT I
Public Nuisance
(Against All Defendants)

537. The Plaintiff Passamaquoddy Tribe–Pleasant Point incorporates herein by reference all the foregoing allegations and further alleges as follows.

538. Defendants' conduct has caused, and continues to cause, a public nuisance by unreasonably interfering with rights common to the general public, including the Passamaquoddy Tribe-Pleasant Point.

[69] National Institute on Drug Abuse, Opioid Overdose Crisis (2018), located at https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis.

539. Defendants, individually and acting through their employees and agents, violated and unreasonably interfered with rights common to the general public, including the Passamaquoddy Tribe–Pleasant Point, by, among other things: (a) interfering significantly with the public health, safety, peace, comfort and convenience of the general community; (b) engaging in conduct proscribed by statute, ordinance or administrative regulation; and (c) engaging in conduct of a continuing nature that Defendants knew or has reason to know, has significant and long-lasting effects upon the public rights of the Passamaquoddy Tribe-Pleasant Point.

540. Each of the Manufacturer Defendants unreasonably interfered with the health, safety, peace and comfort of the Passamaquoddy Tribe–Pleasant Point by, among other things, misleading federal regulators as to the addictive nature of their drugs, promoting and marketing the use of opioids for uses not federally approved, circulating false and misleading information concerning opioids' safety and efficacy, and downplaying or failing to disclose the risk of addiction arising from their use.

541. Defendants' conduct also interfered with the health, safety, peace and comfort of the Passamaquoddy Tribe-Pleasant Point, by causing, among other things, addictions to opioids and other opioid-related negative health, overdoses on opioids resulting in death, sales of illegal opioids and related criminal activities, increased emergency room admissions, increased risks of suicides, costs and expenditures for opioid-related police and social services activities and programs, and other unreasonable interferences with the public's common rights. In so doing, the Defendants acted unreasonably, recklessly and with actual malice.

542. Each of the Defendants also unreasonably interfered with rights common to the general public, including the Passamaquoddy Tribe-Pleasant Point, by engaging in conduct proscribed by statute, ordinance, or administrative regulation, and specifically by failing to design

and operate a system that would disclose the existence of suspicious orders of controlled substances and/or by failing to report suspicious orders of opioids as required by the Controlled Substances Act, 21 C.F.R. §1301.74(b), and by the regulations of the Maine Board of Pharmacy. See 02-392 CMR Pt. 3, Ch. 13, §3 (2), 02-392 CMR Pt. 3, Ch. 16, §2 (8, 10), 02-392 CMR Pt. 5, Ch. 29, §1 (2), and 02-392 CMR Pt. 5, Ch. 30, §1 (13), which incorporate the CSA and its accompanying regulations. In so doing, Defendants acted unreasonably, recklessly and with actual malice.

543. The interference is unreasonable because Defendants' nuisance-creating conduct:

a) Involves a significant interference with the public health, the public safety the public peace, the public comfort, and/or the public convenience;

b) At all relevant times was and is proscribed by state and federal laws and regulations; and/or

c) Is of a continuing nature and, as Defendants know, has had and is continuing to have a significant effect upon rights common to the general public, including the public health, the public safety, the public peace, the public comfort, and/or the public convenience.

544. The significant interference with rights common to the general public is described in detail throughout this Complaint and includes:

a) The creation and fostering of an illegal, secondary market for prescription opioids;

b) Easy access to prescription opioids by children and teenagers;

c) A staggering increase in opioid abuse, addiction, overdose, injuries, and deaths;

d) Infants being born addicted to opioids due to prenatal exposure, causing severe withdrawal symptoms and lasting developmental impacts;

e) Employers have lost the value of productive and healthy employees; and

f) Increased costs and expenses for Plaintiff relating to healthcare services, law enforcement, the criminal justice system, social services, and education systems.

545. Defendants' conduct resulting in the devastating opioid epidemic is continuing and has produced a permanent and long-lasting effect upon the public rights, including those of the Passamaquoddy Tribe–Pleasant Point. Specifically, in light of Defendants' failures to disclose suspicious orders of opioids, and in light of Manufacturer Defendants' aggressive misinformation campaign regarding opioids, the Passamaquoddy Tribe-Pleasant Point was unaware of, and could not reasonably know or have learned through reasonable diligence, that it had been exposed to the risks alleged herein. Information pertaining to the suspicious orders of opioids Defendants were required to disclose—but did not—was nonpublic information over which the Defendants had and continue to have exclusive control, and which Defendants knew was unavailable to the Passamaquoddy Tribe-Pleasant Point.

546. Each Defendant is liable for creating the public nuisance because the intentional and unreasonable and/or unlawful conduct of each Defendant was a substantial factor in producing the public nuisance and harm to Plaintiff.

547. Defendants' intentional and unreasonable nuisance-creating conduct, for which the gravity of the harm outweighs the utility of the conduct, includes:

a) Distributing and selling opioids in ways that facilitated and encouraged their flow into the illegal, secondary market;

b) Distributing and selling opioids without maintaining effective controls against the diversion of opioids;

c) Choosing not to effectively monitor for suspicious orders;

d) Choosing not to investigate suspicious orders;

e) Choosing not to report suspicious orders;

f) Choosing not to stop or suspend shipments of suspicious orders; and

g) Distributing and selling opioids prescribed by "pill mills" when Defendants knew or should have known the opioids were being prescribed by "pill mills."

548. At all times relevant to this Complaint, Defendants were in complete control over the instrumentalities constituting the public nuisance.

549. The Passamaquoddy Tribe–Pleasant Point had neither knowledge nor reason to suspect that the Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment of wrongdoing by the Defendants, the Passamaquoddy Tribe-Pleasant Point could not have reasonably discovered the wrongdoing in time to stem the opioid epidemic in the Passamaquoddy Tribe-Pleasant Point.

550. As detailed herein, Defendants' conduct has interfered with and continues to interfere with rights common to the general public of the Passamaquoddy Tribe-Pleasant Point, and has caused the Passamaquoddy Tribe-Pleasant Point to sustain damages special and different in kind from that suffered by other members of the general public, including, among other special damages, (a) the expenditure of tribal funds and resources to pay for opioid-related increased law enforcement activities, (b) increased costs of health care, (c) increased costs for social services and education, (d) increased substance abuse treatment and diversion plan expenditures, (e) increased emergency and medical care services, (f) increased medical examiner expenditures, and (g) lost economic opportunity, among others.

WHEREFORE, the Passamaquoddy Tribe-Pleasant Point demands judgment against the Defendants for actual and compensatory damages; for restitution; for punitive or exemplary

damages; for costs incurred herein; the cost of abating the public nuisance, and for such other and further relief as this Court deems just and proper.

COUNT II
Negligence
(Against All Defendants)

551. The Plaintiff Passamaquoddy Tribe–Pleasant Point incorporates herein by reference all the foregoing allegations and further alleges as follows.

552. Each of the Defendants herein owed and continue to owe common law and statutory duties to the Passamaquoddy Tribe–Pleasant Point.

553. The Manufacturer Defendants were under a common law duty to conform to a standard of conduct, including the duty to be forthright and honest with the FDA and federal authorities regarding their products; the duty to promote and market opioids truthfully and pursuant to their federally approved indications for use; and the duty to disclose the true risks of addiction associated with the use of Defendants' opioid products.

554. The Manufacturer Defendants breached these common law duties by, among other things, promoting and marketing opioids for uses not federally approved, circulating false and misleading information concerning the safety and efficacy of their opioid products, and downplaying or failing to disclose the risk of addiction arising from their use. In so doing, Defendants acted unreasonably, recklessly and with actual malice. The Manufacturer Defendants' breach of these duties was the proximate cause of the damages suffered by the Passamaquoddy Tribe–Pleasant Point described in this Count.

555. Each of the Defendants also was, and continues to be, under common law and statutory duties imposed by the federal Controlled Substances Act (CSA) and its applicable regulations, as well as duties imposed by the State of Maine which incorporates the CSA and its regulations by and through the regulations of the Maine Board of Pharmacy. See 02-392 CMR Pt.

3, Ch. 13, §3 (2), 02-392 CMR Pt. 3, Ch. 16, §2 (8, 10), 02-392 CMR Pt. 5, Ch. 29, §1 (2), and 02-392 CMR Pt. 5, Ch. 30, §1 (13).

556. The Defendants breached their common law and statutory duties by, among other things:

a) Distributing and selling opioids in a manner which facilitated and encouraged their movement into the illegal, secondary market;

b) Distributing and selling opioids without maintaining effective controls against diversion of the opioids pursuant to 21 C.F.R. § 1301.71(a), 02-392 CMR Pt. 5, Ch. 29, §1 (2), 02-392 CMR Pt. 5, Ch. 30, §1 (13), and 32 MSRA §13742-A(1)(C);

c) Failing to be responsible legally and professionally for all activities related to the practice of pharmacy within the retail pharmacy for which the licensee is registered, 02-392 CMR Pt. 5, Ch. 13, §3 (2);

d) Failing to conform their conduct to various federal statutes, including the federal Food, Drug and Cosmetics Act (FDCA), 21 U.S.C. §301 *et seq.*, the Drug Abuse and Prevention Control law, including but not limited to the CSA, 21 U.S.C §801 *et seq.*, and its applicable regulations, 21 CFR Parts 1300-1301, 1302, 1304-14, 02-392 CMR Pt. 5, Ch. 29, §1(1, 2, 6), §2;

e) Failing to comply with the provisions of the Maine Pharmacy Act, the rules and regulations of the Maine Board of Pharmacy, and the federal laws and rules specified in Chapter 29, Section 1 of the board's rules." See 02-392 CMR Pt. 3, Ch. 13, §3 (2), 02-392 CMR Pt. 3, Ch. 16, §2 (8, 10), 02-392 CMR Pt. 5, Ch. 29, §1 (1-10), and 02-392 CMR Pt. 5, Ch. 30, §1;

f) Failing to provide effective controls and guard against theft and diversion of controlled substances, pursuant to 21 C.F.R. § 1301.71(a), 02-392 CMR Pt. 5, Ch. 29, §1 (2, 6), 02-392 CMR Pt. 5, Ch. 30, §1(13, 15, 17), 32 MSRA §13742-A(1)(C);

g) Failing to "establish controls against diversion of prescription drugs into other than legitimate medical, scientific, or industrial channels." See 02-392 CMR Pt. 5, Ch. 30, §1 (13);

h) Failing to prevent the filling and dispensing of prescriptions without a legitimate purpose as required under 21 C.F.R. § 1306.04; 02-392 CMR Pt. 5, Ch. 30, §1(13);

i) Filling opioid prescriptions that would have been deemed questionable or suspicious by a reasonably prudent pharmacy, 21 C.F.R. § 1306.04, 02-392 CMR Pt. 5, Ch. 30, §1(13-17);

j) Failing to report suspicious or invalid orders of controlled prescription drugs to the appropriate regulators;

k) Failing to adequately investigate suspicious orders before filling them;

l) Failing to design and operate a system that would disclose the existence of suspicious orders of controlled substances;

m) Failing to adequately monitor suspicious opioid orders;

n) Failing to maintain effective controls against potentially illegitimate orders and diversion of controlled substances, including prescription opioids *See* 21 C.F.R. § 1301.71(a), 02-392 CMR Pt. 5, Ch. 30, §1 (13);

o) Failing to adequately train and supervise their employees at the point of sale to investigate or report suspicious or invalid prescriptions;

p) Failing to protect against corruption or theft by its employees or agents. 02-392 CMR Pt. 5, Ch. 29, §1 (2);

q) Promoting unsafe dispensing in the interest of speed.

557. In so doing, the Defendants acted unreasonably, recklessly and with actual malice.

558. Each of the Defendants' violations of the aforementioned federal statutes and regulations, as well as their violations of the aforementioned Maine statutes and regulations, are clear evidence of negligence.

559. It was reasonably foreseeable that Defendants' actions and omissions would result in the harms suffered by the Plaintiff Passamaquoddy Tribe–Pleasant Point described herein.

560. The Plaintiff Passamaquoddy Tribe–Pleasant Point suffered injuries and pecuniary losses proximately caused by Defendants' breaches of their common law and statutory duties set forth in this Count. Among other things, the Tribe's members are suffering through an unprecedented epidemic of opioid addiction and overdose. This epidemic has forced the Tribe to shoulder tremendous opioid-related costs relating to, among other things, health and medical services, emergency services, detox and addiction treatment services, social services, law enforcement, loss of productivity in its workforce, and other costs from the cascading effects of the opioid epidemic.

561. Defendants' breaches of the common-law and statutory duties they owed to the Passamaquoddy Tribe–Pleasant Point are the proximate cause of this opioid crisis and of all the damages and harms suffered by the Passamaquoddy Tribe-Pleasant Point.

WHEREFORE, the Plaintiff Passamaquoddy Tribe-Pleasant Point demands judgment against the Defendants for actual and compensatory damages; for restitution; for punitive or

exemplary damages; for costs incurred herein; and such other and further relief as this Court deems just and proper.

COUNT III
Unjust Enrichment
(Against All Defendants)

562. The Passamaquoddy Tribe-Pleasant Point incorporates herein by reference the foregoing allegations as though fully set forth herein.

563. The Passamaquoddy Tribe-Pleasant Point has expended substantial amounts of money and Tribal resources—including opioid-related costs of the Tribal police force, health clinic, medical costs, increased emergency room visits, addiction treatment, pharmacy costs, behavioral health and substance abuse counseling, lost productivity, and other Tribal costs. These expenditures were necessitated in an effort to remedy and mitigate the various societal harms and costs caused to the Tribe by the opioid crisis which was triggered by Defendants' misconduct pertaining to opioids, including their misleading statements pertaining to the risks of their opioid products, their deceptive marketing, and their deliberate disregard of their obligations to prevent diversion and abuse of their opioid products.

564. These expenditures by the Passamaquoddy Tribe-Pleasant Point enabled the Defendants to reap billions of dollars in profits from their manufacture, sale, distribution, and diversion of their opioid products, thereby conferring a benefit upon the Defendants.

565. Defendants appreciated and knew the financial benefit being conferred upon them by their misrepresentations, deceptive marketing, and failure to prevent diversion and abuse of their opioid products.

566. Further, each Manufacturing Defendant and Distributor Defendant retained the benefits – i.e., the payments for opioids purchased therefrom – when it was unjust to do so, as the

provision of opioids to Plaintiff, Plaintiff's agents, Plaintiff's community, the public, and persons on whom Plaintiff and its agents relied caused cataclysmic harm to Plaintiff, Plaintiff's community, and the public. All Defendants retained the money they received from Plaintiff, Plaintiff's agents, Plaintiff's community, the public, and persons on whom Plaintiff and its agents relied, when in justice and in equity that money belongs to them, and it would be unjust to allow Defendants to retain that benefit. Defendants' revenues were made, in part, at the expense of Plaintiff.

567. Defendants were unjustly enriched under these circumstances and therefore it would be inequitable for them to retain the billions of dollars in profits they reaped from their manufacture, sale, distribution, and diversion of their opioid products caused by their misleading statements and omissions, deceptive marketing, and failure to prevent diversion and abuse of their opioid products.

568. In exchange for the opioid purchases, and at the time Plaintiff and its residents made these payments, Plaintiff and its residents expected that Defendants had provided all of the necessary and accurate information regarding those risks and had not misrepresented any material facts regarding those risks.

569. As an expected and intended result of their own conscious wrongdoing, Defendants caused the unjustness of the benefit they knowingly received and have profited thereby. They benefited from opioid purchases that Plaintiff and its residents made as a result of Defendants' conduct, as set forth in this Complaint, including Defendants' false marketing and failure to report suspicious sales.

570. It would be inequitable under these circumstances for the Defendants to retain this benefit without paying Plaintiff for its value. Plaintiff seeks recovery of the benefit it conferred upon Defendants and by which Defendants were enriched as a result of their inequitable conduct

WHEREFORE, Plaintiff Passamaquoddy Tribe-Pleasant Point hereby seek recovery and disgorgement of the amounts and profits by which the Defendants were unjustly enriched as a result of their misconduct and such other and further relief as this Court deems just and proper.

COUNT IV
Fraud and Misrepresentation
(Against All Defendants)

571. The Plaintiff Passamaquoddy Tribe–Pleasant Point incorporates herein by reference all the foregoing allegations and further alleges as follows.

572. Defendants knowingly made numerous misrepresentations and omissions of material fact regarding the safety and effectiveness of their opioid products as set forth hereinabove which are fully incorporated in this Count.

573. Manufacturing Defendants violated their duty not to actively deceive by intentionally and unlawfully making knowingly false statements and intentionally and unlawfully omitting and/or concealing information that made statements Defendants did make knowingly false.

574. Specifically, the Manufacturing Defendants' deceptions during the relevant period include, but are not limited to:

a) Manufacturing Defendants' misrepresentations that the risks of long-term opioid use, especially the risk of addition, were overblown;

b) Manufacturing Defendants' misrepresentations that opioid doses can be safely and effectively increased until pain relief is achieved;

c) Manufacturing Defendants' misrepresentations that signs of addiction were "pseudoaddiction" and thus reflected undertreated pain, which should be responded to with more opioids;

d) Manufacturing Defendants' misrepresentations that screening tools effectively prevent addiction;

e) Manufacturing Defendants' misrepresentations concerning the comparative risks of NSAIDs and opioids;

f) Manufacturing Defendants' misrepresentations that opioids differ from NSAIDs in that opioids have no ceiling dose;

g) Manufacturing Defendants' misrepresentations that evidence supports the long-term use of opioids for chronic pain;

h) Manufacturing Defendants' misrepresentations that chronic opioid therapy would improve patients' function and quality of life;

i) Purdue and Endo's misrepresentations that abuse-deterrent opioids reduce tampering and abuse;

j) Purdue's misrepresentations that OxyContin provides a full 12 hours of pain relief;

k) Purdue's misrepresentations that it cooperates with and supports efforts to prevent opioid abuse and diversion;

l) Insys's misrepresentations that Subsys was appropriate for treatment of non-cancer pain and its failure to disclose that Subsys was not approved for such use;

m) Teva's misrepresentations that Actiq and Fentora were appropriate for treatment of non-cancer pain and its failure to disclose that Actiq and Fentora were not approved for such use;

n) Insys's misrepresentations to third-party payors to secure approval for coverage;

o) Insys's use of speakers bureaus to disguise kickbacks to prescribers; and

p) Manufacturing Defendants' use of front groups to misrepresent that the deceptive statements from these sources described in this Complaint came from objective, independent sources.

575. Defendants made such misrepresentations and omissions regarding their opioid products knowingly or in reckless disregard of their truth or falsity.

576. Defendants falsely represented, failed to disclose, and omitted the dangers and risks of their opioid products, including the dangers and risks of misuse, addiction, and diversion.

577. Defendants further made false statements regarding their compliance with state and federal law and specifically regarding their duties to monitor, report and prevent suspicious orders and prescriptions for their opioid products, as well as their duties to prevent diversion.

578. By engaging in the acts and practices alleged herein, Manufacturing Defendants omitted material facts, with the intent that others rely on their omissions or suppression of information, that they had a duty to disclose by virtue of these Defendants' other representations, including, but not limited to, the following:

a) opioids are highly addictive and may result in overdose or death;

b) no credible scientific evidence supports the use of screening tools as a strategy for reducing abuse or diversion;

c) high dose opioids subject the use to greater risks of addiction, other injury, or death;

d) the risks of hyperalgesia, hormonal dysfunction, decline in immune function, mental clouding, confusion, dizziness, increased falls and fractures in the elderly, neonatal abstinence syndrome, and potentially fatal interactions with alcohol or

benzodiazepines, particularly while exaggerating the risks of competing products, such as NSAIDs;

e) claims regarding the benefits of chronic opioid therapy lacked scientific support or were contrary to the scientific evidence;

f) Purdue's 12-hour Oxycontin fails to last a full 12 hours in many patients;

g) Purdue and Endo's abuse-deterrent formulations are not designed to address, and have no effect on, the most common route of abuse (oral abuse), can be defeated with relative ease; and may increase overall abuse;

h) Manufacturing Defendants failed to report suspicious prescribers and orders;

i) Insys's use of kickback and insurance fraud schemes; and

j) Manufacturing Defendants' failure to disclose their financial ties to and role in connection with Key Opinion Leaders ("KOLs") and front groups.

579. Defendants, as manufacturers and distributors of a highly dangerous and addictive opioid product—a product used for medical purposes which was and is highly regulated under federal and state law—were in a special relationship with doctors, patients, and entities such as the Plaintiff Passamaquoddy Tribe–Pleasant Point, a relationship in which the purchasers and users of such dangerous products, as well as entities such as the Plaintiff Passamaquoddy Tribe–Pleasant Point which provides health, social, police, and other services to its members, placed a high level of trust and reliance on the representations of the Defendants to be truthful and that Defendants not deceive Plaintiff or fail to disclose materials facts regarding their opioid products.

580. The Defendants made such representations for the purposes of inducing doctors, patients, and the Plaintiff Passamaquoddy Tribe–Pleasant Point, including its tribal members, to

rely on such representations and thus for doctors and patients to prescribe and use, and entities such as Plaintiff herein to provide services, related to Defendants' opioid products. '

581. Defendants further violated their general duty not to actively deceive, have made knowingly false statements, and have omitted and/or concealed information that made statements Defendants did make knowingly false. Defendants acted intentionally and/or unlawfully.

582. Defendants had a duty to disclose the above-referenced material facts and concealed them. These false representations and concealed facts were material to the conduct and actions at issue. Defendants made these false representations and concealed facts with knowledge of the falsity of their representations and did so with the intent of misleading Plaintiff, Plaintiff's community, the public, the medical profession, and persons on whom Plaintiff relied.

583. These false representations and omissions were calculated to deceive Passamaquoddy Tribe–Pleasant Point and its tribal members and did in fact deceive these persons and the Passamaquoddy Tribe–Pleasant Point.

584. Plaintiff relied on Defendants' representations and/or omissions, both directly and indirectly.

585. Defendants' fraudulent conduct, false representations, and omission were the proximate cause of all the injuries and harms alleged by Plaintiff.

586. Defendants are also liable for negligent misrepresentation because they supplied false information regarding the safety and efficacy of their opioid products and in so doing failed to exercise reasonable care or competence in obtaining or communicating such information. Defendants are also liable because the false information regarding their opioid products which they supplied was justifiably relied upon by others and caused others to suffer pecuniary losses.

WHEREFORE, the Plaintiff Passamaquoddy Tribe-Pleasant Point demands judgment against the Defendants for actual and compensatory damages; for restitution; for punitive or exemplary damages; for costs incurred herein; the cost of abating the public nuisance, and for such other and further relief as this Court deems just and proper.

COUNT V
Civil Conspiracy
(Against All Defendants)

587. Defendants engaged in a civil conspiracy to commit fraud and misrepresentation in their marketing, sales, and distribution of their opioid products.

588. Defendants expressly or impliedly agreed amongst themselves to engage in a concerted action to perpetrate a fraud upon the Passamaquoddy Tribe by the unlawful distribution and diversion of their opioid products into the Passamaquoddy Tribe–Pleasant Point and among its tribal members.

589. The purpose of Defendants' concerted action was to accomplish a criminal or unlawful goal or to accomplish a lawful purpose by the use of criminal or unlawful means.

590. Defendants conspired among themselves in furtherance of a course of action intended to flood the market with their opioid products in order to generate massive profits by the sale of such products.

591. The Marketing Defendants engaged in a nationwide conspiracy to make false representations and omissions regarding the safety and efficacy of their opioid products to induce medical practitioners to prescribe their opioids products for inappropriate medical purposes, including, specifically, for the treatment of chronic, non-cancer pain.

592. The Marketing Defendants further conspired to conceal from medical practitioners, patients, the Plaintiff Passamaquoddy Tribe and its members the risks of misuse, addiction, and diversion of their opioid products.

593. The Marketing Defendants' benefited from their conspiracy which did in fact generate substantial profits for the Defendants and their co-conspirators.

594. Defendants' conspiracy and acts are also alleged in greater detail in Plaintiff's racketeering allegations under RICO (Count VI) and are incorporated herein.

595. Defendants also unlawfully failed to act to prevent the fraud and failed to monitor, report, and prevent suspicious orders and diversions of their opioid products.

596. Defendants acted with a common understanding and design to commit unlawful acts as alleged, acted purposefully, and without reasonable or lawful excuse, which proximately caused the harms and injuries alleged herein.

597. Defendants' conspiracy was the foreseeable cause of the harms and injuries alleged herein.

598. Defendants acted with malice, purposefully, unlawfully, and without reasonable excuse, by engaging in this conspiracy.

599. Each of the Defendants committed the tortious acts described herein in concert with each other and their co-conspirators.

600. As a direct and proximate result of Defendants' conspiracy to commit fraud and their illegal, wrongful, or tortious conduct, the Plaintiff Passamaquoddy Tribe–Pleasant Point has been injured and sustained damages.

WHEREFORE, the Plaintiff Passamaquoddy Tribe-Pleasant Point demands judgment against the Defendants for actual and compensatory damages; for restitution; for punitive or

exemplary damages; for costs incurred herein; and such other and further relief as this Court deems just and proper.

COUNT VI
Violations of Racketeer Influenced And Corrupt Organizations Act 18 U.S.C. 1961, *et seq.* (RICO)

601. The Plaintiff Passamaquoddy Tribe–Pleasant Point incorporates herein by reference all the foregoing allegations and further alleges as follows.

602. The Passamaquoddy Tribe–Pleasant Point brings this count on behalf of itself against the Manufacturer Defendants, the Distributor Defendants, and the Retailer Defendants (collectively, the "RICO Defendants").

603. Under RICO it is "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. §1962(c).

604. RICO also makes it unlawful for "any person to conspire to violate" the provisions of 18 U.S.C. §1962(c). 18 U.S.C. §1962(d).

605. At all relevant times, the RICO Defendants have been and are "persons" because they are capable of holding, and do hold, a "legal or beneficial interest in property." 18 U.S.C. §1961(3).

606. The RICO Defendants herein are culpable persons who have violated RICO because, as set forth herein, they willfully and knowingly committed and conspired to commit a racketeering activity through a pattern involving an enterprise or association in fact which affected interstate commerce.

607. The RICO Defendants conducted and continue to conduct their business through both legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise.

608. Each RICO Defendant belongs to a subgroup of defendants, of which each subgroup forms an association-in-fact enterprise or a legal enterprise (each, a "Dealing Enterprise").

609. The Plaintiff Passamaquoddy Tribe–Pleasant Point suffered injuries which were caused by the RICO Defendants' commission of the predicate acts alleged herein, including, among others, mail fraud and wire fraud.

610. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused the Passamaquoddy Tribe–Pleasant Point's injuries. As a result of the opioid epidemic resulting from the RICO Defendants' violations of federal and state law, the Passamaquoddy Tribe–Pleasant Point suffered losses and incurred expenses which include, but are not limited to:

a) Expenditures to provide health services, mental-health services, and social services to victims of the opioid epidemic and their families, including expenses incurred by the Passamaquoddy Tribe–Pleasant Point in connection with the provision of services well beyond those required during the period predating the opioid epidemic;

b) Expenditures relating to law-enforcement attempts to stem the flow of opioids and heroin into local communities, to arrest and prosecute street-level dealers, to otherwise prevent the current opioid epidemic from spreading and worsening, and to deal with increased levels of other crimes, such as minor and major violence,

burglary, robbery, and other crimes, which has directly resulted from an increase in the size of the homeless and drug-addicted population;

c) Expenditures associated with training first responders on how to treat drug overdoses;

d) Losses caused by decreased productivity of employees of the Passamaquoddy Tribe—Pleasant Point at work who are plagued with issues caused by opioid use and abuse;

e) Losses caused by diminished property values in neighborhoods where the opioid epidemic, and the heroin trade, have taken root;

f) Expenditures associated with treating infant children who are born addicted to opioids due to drug use by mothers during pregnancy;

g) Loss of funding for important public services for which the funding was slashed and/or diverted to other public services designed to address the opioid epidemic;

h) Expenditures associated with tribal judicial operations;

i) Expenditures associated with providing police officers, firefighters, and emergency responders with Naloxone—an opioid antagonist used to block the deadly effects of opioids in the context of overdose;

j) Costs incurred by the Passamaquoddy Tribe–Pleasant Point and its Emergency Medical Services Division in connection with emergency responses to opioid overdoses;

k) Past expenses incurred by the Passamaquoddy Tribe–Pleasant Point in connection with drug treatment services in the Passamaquoddy Tribe–Pleasant Point,

including, but not limited to, the administration of a methadone maintenance/detox program with clinics capable of servicing patients at each site;

l) Expenses incurred by the Passamaquoddy Tribe–Pleasant Point to address homelessness, blight, and transiency caused by the opioid epidemic.

611. The RICO Defendants' racketeering activities were the factual cause of the Passamaquoddy Tribe–Pleasant Point's damages because the Passamaquoddy Tribe–Pleasant Point would not have incurred the expenditures and losses associated with the opioid epidemic but for the RICO Defendants' racketeering activities and operation of their enterprise. Nor would the Passamaquoddy Tribe–Pleasant Point have incurred any of the other costs associated with the plague of addiction caused by the RICO Defendants' opioid drugs.

612. The Passamaquoddy Tribe–Pleasant Point has standing to bring this civil RICO action because its injuries were directly and proximately caused by the RICO Defendants' violations of law and their pattern of racketeering activity.

613. The Passamaquoddy Tribe–Pleasant Point seeks all legal and equitable relief available under the law, in the maximum amount and to the furthest extent permitted by law.

A. OPIOID MARKETING ENTERPRISE

614. The Manufacturer Defendants and their co-conspirators engaged in a coordinated conspiracy to deceive the American public and the medical profession about the efficacy and safety of opioids, including by minimizing the addictive qualities of opioids. That conspiracy is referred to the "Marketing Enterprise," or, for purposes of this subsection, the "Enterprise."

615. The formation, existence, and actions of the Marketing Enterprise were essential to the success of Manufacturer Defendants' campaign to increase and maintain profits from unlawful sales of opioids. The constituent members of the Marketing Enterprise were aware that, unless

they agreed to act and acted as an enterprise, their sales of prescription opioids would substantially decrease, and accordingly, the profits of the Manufacturer Defendants would substantially diminish.

616. At all relevant times, the Marketing Enterprise has existed separate and apart from defendants' racketeering acts and their conspiracy to commit such acts. The Marketing Enterprise has an ascertainable structure and purpose beyond the scope and commission of defendants' predicate acts. It has a consensual decision making structure that is used to coordinate strategy, manipulate scientific data, suppress the truth about the addictive qualities of opioids, and otherwise further the Manufacturer Defendants' fraudulent unified scheme.

617. The Manufacturer Defendants' conduct, and that of their co-conspirators, has been directed in a uniform manner—using the same misleading and deceptive drug labels and same misleading and deceptive promotional practices.

618. Manufacturer Defendants' deceptive and misleading marketing scheme increased the number of prescriptions of opioids written and filled over the last two decades. Because Defendants withheld material information about the true safety and efficacy of opioids, prescribing physicians did not have the knowledge necessary to make informed decisions regarding opioid prescriptions. Physicians thus wrote prescriptions they would not have otherwise, and the Passamaquoddy Tribe–Pleasant Point, unaware of Manufacturer Defendants' scheme, was left to pay for the resulting opioid epidemic.

619. Effective, safe, and less expensive alternatives to opioids are available. Yet Manufacturer Defendants were able to dominate the market for pain-relief by funding and carrying out an aggressive misinformation campaign about opioid safety and effectiveness. As a result of that campaign—which sparked the opioid epidemic and its widespread devastation—

Manufacturer Defendants raked in billions of dollars in profits. Those are ill-gotten gains to which they are not entitled.

620. Patients relied on Manufacturer Defendants' misrepresentations regarding opioids safety and efficacy when making purchases of the drugs. Physicians relied on Manufacturer Defendants' misrepresentations regarding opioids safety and efficacy when prescribing the drugs for their patients. From both groups, Manufacturer Defendants withheld material information about the drugs' safety and efficacy that was not otherwise available and undercut the entire rationale for their use.

621. The Marketing Enterprise functioned as an ongoing organization and continuing unit. The Marketing Enterprise was created and/or used as tools to effectuate a pattern of racketeering activity. Each of the Marketing Enterprise participants, including Defendants, is a "person" distinct from the Marketing Enterprise.

622. Each of the Defendants, in concert with the other Enterprise participants, created and maintained systematic links for a common purpose, i.e., to aid in marketing opioids as effective and safe for use by patients in moderate pain, while suppressing evidence to the contrary. Each of the participants in the Marketing Enterprise received revenue, directly or indirectly, and/or otherwise benefitted from the scheme to promote opioids as safe and non-addictive. Such revenue was exponentially greater than it would have been had opioids been marketed appropriately and the true efficacy and safety risks of prescription opioids disclosed. All participants of the Marketing Enterprise were aware of Defendants' control over the activities of the Enterprise in promoting opioids for use in every situation in which a patient is in pain. Furthermore, each portion of the Enterprise benefited from the existence of the other parts.

623. Defendants established the Marketing Enterprise to accomplish goals that were instrumental to its scheme designed to market and sell opioids in every situation in which a patient is in pain.

624. In order to further the conspiracy, and as part of an Enterprise that was engaged in a pattern of racketeering activity, Defendants formed multiple front groups or infiltrated existing third party organizations to avoid regulation from the FDA.

a) The American Pain Foundation ("APF"), founded in 1997, described itself as the nation's largest advocacy group for pain patients. At the heart of its messaging was that the risk of opioid addiction was overblown and opioids were underused as a treatment for pain. In December 2011, a ProPublica investigation found that in 2010, nearly 90% of APF's funding came from the drug and medical device community, including Manufacturer Defendants. On May 8, 2012, the U.S. Senate Finance Committee sent a letter APF inquiring about its ties to drug manufactures. That very same day, APF announced it was ceasing operations, effective immediately. APF, upon information and belief, received more than $10 million in funding from opioid manufacturers from 2007 through 2012. The primary opioid manufacturer contributors were Purdue and Endo. Manufacturer Defendants Purdue, Endo, Janssen and Cephalon all contributed to funding APF;

b) The American Academy of Pain Management ("AAPM") is a medical specialty society which has received funding from Manufacturer Defendants for years. Upon information and belief, Endo, Janssens and Purdue have contributed funding to AAPM. AAPM issued a statement in 1997 that endorsed opioids, and claimed that the risk of opioid addiction in people taking prescription opioids was low. The

chairman of AAPM at that time was Dr. David Haddox. Dr. Haddox was, at the time of the statement, a paid speaker for Purdue. He later went on to become Purdue's vice president for health policy and is most known for inventing the pseudoscience of pseudoaddiction (the idea that opioid-seeking patients are not actually addicted to opioids but are "undertreated"—requiring higher doses of opioids.);

c) In 2009, the American Pain Society ("APS") and AAPM jointly issued guidelines ("APS/AAPM Guidelines") recommending the use of opioids to treat chronic pain. The APS/AAPM guidelines promoted the use of opioids for the treatment of chronic pain and concluded that the risk of opioid addiction was manageable in patients regardless of previous histories of abuse. At least fourteen of the twenty-one panel members who drafted the APS/AAPM Guidelines received funding from manufacturer defendants Purdue, Endo, Cephalon or Janssen;

d) FSMB printed and distributed "Responsible Opioid Prescribing," a guide authored by Dr. Scott Fishman in 2007 on behalf of the Manufacturer Defendants. FSMB received funding from organizations that manufacture opioid-based drugs from 1997 through 2012. Included in the list of payments are Manufacturer Defendants Purdue, Endo, Cephalon and Mallinckrodt. Total disclosed payments include $822,400.06 from Purdue, $371,620.00 from Endo, $180,000.00 from Cephalon and $100,000.00 from Mallinckrodt;

e) The Pain Care Forum ("PCF") is a coalition comprised of Manufacturer Defendants, trade groups, and various front groups supported by the pharmaceutical industry. Purdue, Endo, Cephalon and Janssen are each represented in PCF. Upon

information and belief, Distributor Defendants participated directly in PCF as well. PCF projects included making sure that a FDA mandated education project on opioids did not require mandatory participation by prescribers, since manufacturer defendants determined this would reduce opioid prescribing habits; and

f) Healthcare Distribution Alliance ("HDA") is an association of pharmaceutical manufacturers and distributors. Upon information and belief, members of the HDA included Manufacturer Defendants Purdue, Endo, Johnson & Johnson (Janssen's parent company), Actavis, and Teva (Cephalon's parent company), and distributor defendants McKesson, Cardinal Health, and AmerisourceBergen.

625. The Marketing Enterprise used three principle stratagems to facilitate their goal of misleading doctors and the public about the dangers opioids. *First*, using the shadow groups discussed above, the Marketing Enterprise created a marketing structure that appeared independent from Manufacturer Defendants. In so doing, Manufacturer Defendants sought to avoid federal regulations concerning off-label promotion. *Second*, Manufacturer Defendants generated and published favorable articles that appeared to emanate from independent physicians. *Third*, in order to widely disseminate the message that opioids were practically non-addictive, Defendants' marketing enterprise developed misleading labeling. That labeling was widely disseminated across the country to physicians and prescribers. These three stratagems were complementary and mutually reinforcing. The production of favorable publications and the peer-to-peer marketing and promotion allowed aggressive sales pitches to continue with the appearance of legitimacy.

626. There was a common strategy employed by these Enterprise participants whereby the Enterprise participants would recruit and use physicians, both for marketing and publication,

to promise the ubiquitous use of opioids. That created the perception that independent physicians were achieving favorable results with opioids with little to no incidence of addiction.

627. The various participants of the Enterprise performed work that Manufacturer Defendants could not lawfully do, including funneling payments to physicians, misleading the public into believing the message was coming from a neutral source, covering up Manufacturer Defendants' control over the Enterprises, and actively concealing any negative information.

628. These systematic linkages between physicians, marketing participants, physician participants, Manufacturer Defendants and all the Enterprise participants were established for a common purpose: to aid in marketing and selling opioids for ubiquitous use to treat all levels of pain. Many of the Enterprise participants received substantial revenue from the scheme to promote opioids. Such revenue was exponentially greater than it would have been if opioids been marketed appropriately.

629. All participants of the Enterprise were fully aware of Manufacturer Defendants' control over the Enterprise. Furthermore, each portion of the Enterprise benefited from the existence of other parts. For example, medical "experts" and "thought leaders" on the Enterprise's payroll produced literature promoting opioids—which, in turn, provided medical legitimacy to the Enterprise's direct-to-prescriber promotional materials.

630. The Marketing Enterprise are engaged in interstate commerce, or their activities affect interstate commerce, because many of the Enterprise's activities (a) involved promotion of opioid sales between and/or among residents of different states, and/or (b) physical transportation of promotional materials across state lines.

631. The named Manufacturer Defendants exerted control over the Enterprise, and Defendants have participated in the operation or management of the affairs of the Enterprise.

632. The Manufacturer Defendants' predicate acts of racketeering, 18 U.S.C. § 1961(1) include, but are not limited to:

a) Mail Fraud: The Manufacturer Defendants violated 18 U.S.C. § 1341 by sending and receiving, and by causing to be sent and/or received, materials via U.S. Mail or commercial interstate carriers for the purpose of executing the unlawful scheme to deceptively market, and sell the opioids by means of false pretenses, misrepresentations, promises and omissions; and

b) Wire Fraud: The Manufacturer Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, and by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to defraud and obtain money on false pretenses, misrepresentations, promises and omissions.

633. The Manufacturer Defendants' use of the mails and wires include, but are not limited to, the transmission, delivery and shipment of deceptive marketing materials by the Manufacturer Defendants and other members of the opioid marketing fraud enterprise. These materials would not have been delivered but for the Manufacturer Defendants' illegal scheme, including, but not limited to:

a) false or misleading communications to the public and to regulators;

b) sales and marketing materials, including slide decks, presentation materials, purported guidelines, advertising, web sites, product packaging, brochures, labeling and other writings which misrepresented, falsely promoted and concealed the true nature of opioids;

c) Numerous guides and brochures for patients, doctors, and policymakers produced by the American Pain Foundation that minimizing the risks of addiction and

exaggerated the benefits associated with prescription opioids, including but not limited to the "Policymaker's Guide," sponsored by Purdue, which sought to dispel the "myth" that opioid pain medication leads to addition, "Exit Wounds: A Survival Guide to Pain Management for Returning Veterans & Their Families," sponsored by Endo, which falsely claimed that it is unlikely that people who are not predisposed to addiction will become addicted to opioid painkillers, and "Treatment Options: A Guide for People Living with Pain," which promoted opioids as essential for treating even "moderate" pain.

d) Statements by the American Academy of Pain Management that endorsed opioids and claimed that the risk of opioid addiction in people taking prescription opioids was low.

e) Guidelines issued in 2009 by the American Pain Society ("APS") and American Academy of Pain Management ("AAPM") recommending the use of opioids to treat chronic pain. The APS/AAPM guidelines promoted the use of opioids for the treatment of chronic pain and concluded that the risk of opioid addiction was manageable in patients regardless of previous histories of abuse.

f) Distribution of "Responsible Opioid Prescribing," a guide authored by Dr. Scott Fishman in 2007. The guide was ultimately disseminated to 700,000 practicing doctors, including physicians in Maine. The "Responsible Opioid Prescribing" guide promoted the use of opioid pain relievers for both acute and chronic pain and severely minimized the risk of addiction—even claiming that opioids could be used safely in patient assessed to have a risk of substance abuse. The guide promoted the widespread use of opioids, stating that "[p]atients should not be denied opioid

medications except in light of clear evidence that such medications are harmful to the patient."

634. Further, the RICO Defendants conducted and participated in the conduct of the affairs of the Opioid Marketing Enterprise through a pattern of racketeering activity as defined in, and in violation of, 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States. Furthermore, in so doing the acts alleged herein, the members of the Enterprises (the "Co-Conspirators") conspired to violate § 1962(c) of the RICO Act, and they thereby violated § 1962(d) of the RICO Act.

635. Specifically, the Defendants violated 21 U.S.C. § 843(a)(4) by knowingly and intentionally furnishing false information in, and omitting material information from, reports, records, and other documents required to be made, kept, and filed under the relevant subchapter of Title 21 of the United States Code. Such a violation of 21 U.S.C. § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

636. The Defendants also violated 18 U.S.C. § 1952, pertaining to interstate and foreign travel or transportation in aid of racketeering enterprises (the "Travel Act), because they used the mail and facilities in interstate commerce (i.e., interstate wires) with the intent to promote, carry on, or facilitate the promotion or carrying on of, "any unlawful activity" within the meaning of 18 U.S.C. § 1952(b), namely, a business enterprise involving narcotics or controlled substances, and thereafter performed or attempted to perform any such unlawful activity, including the foregoing violations of federal law as well as violations of the laws of the State of Maine. Specifically, as set

forth hereinabove, the Defendants violated various and numerous provisions of the Maine Pharmacy Act, 32 MSRA § 13701 *et seq*.

637. The conduct of the Enterprise described above constitutes "racketeering activity" within the meaning of 18 U.S.C. § 1961(1). Manufacturer Defendants' decision for the Enterprise to routinely conduct its transactions in such a manner constitutes a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

638. The above described racketeering activities amounted to a common course of conduct intended to deceive and harm the general public and the Passamaquoddy Tribe–Pleasant Point. Manufacturer Defendants' racketeering activity was related, had similar purposes, involved similar or the same participants, and methods of commission, and had similar results affecting the same or similar victims, including the Passamaquoddy Tribe–Pleasant Point. Defendant's racketeering activities were part of their ongoing business and constitute a continuing threat to the property of the Passamaquoddy Tribe–Pleasant Point.

639. Manufacturer Defendants' motive in creating and operating the fraudulent scheme and the Enterprises was to obtain additional revenues from the marketing and sale of opioids for treating every conceivable level of patient pain.

640. The Passamaquoddy Tribe–Pleasant Point has been injured in their property by reason of these violations in that the Passamaquoddy Tribe–Pleasant Point has paid and will pay millions of dollars to abate the public nuisance that is the opioid epidemic in the Passamaquoddy Tribe–Pleasant Point.

641. Defendants' racketeering activity was a substantial factor in bringing about injuries to the Passamaquoddy Tribe—Pleasant Point. In the absence of the Manufacturer Defendants'

unlawful conduct, the American public and the American medical community would not have been misled as to the addictive qualities of opioids.

642. The Enterprise, and the members thereof, acted and participated to further the purpose of the Enterprise willfully and/or with actual knowledge of the illegal acts of the enterprise, as evidenced by their aggressive marketing campaigns and even recent activities abroad, which includes companies owned and controlled by Purdue running training seminars where doctors are urged to overcome "opiophobia" and prescribe painkillers.[70]

643. The RICO Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other persons, firms, and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the RICO Defendants and have performed acts in furtherance of the scheme to increase revenues, increase market share, and/or minimize the losses for the RICO Defendants.

644. The RICO Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme, and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

645. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

646. As described herein, the RICO Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues from the

[70] Harriet Ryan, Lisa Girion & Scott Glober, *OxyContin goes Global – ""We're only just getting started"*, LOS ANGELES TIMES (Dec. 18, 2016), http://www.latimes.com/projects/la-me-oxycontin-part3/.

sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

647. The predicate acts all had the purpose of generating significant revenue and profits for the RICO Defendants. At the same time, the Passamaquoddy Tribe–Pleasant Point was forced to shoulder costs related to the damage that the prescription opioid epidemic caused.

648. The pattern of racketeering activity alleged herein, and the Enterprises alleged herein (including both the Opioid Marketing Enterprise and the Diversion Enterprise) are separate and distinct from each other. Likewise, Defendants are distinct from the Enterprises.

649. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

650. The Co-Conspirators so conspired because there was a meeting of the minds evidencing the alleged conspiracy of which the intent was to violate § 1962(c).

651. The Opioid Marketing Enterprise and the Diversion Enterprise did encourage, and indirectly create, contribute to, and maintain an illegal secondary market for opioids.

652. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

653. But for the conduct of the Enterprises' affairs, the Passamaquoddy Tribe–Pleasant Point would not have sustained damages.

654. The Passamaquoddy Tribe–Pleasant Point's damages are not remote. Nor are the Passamaquoddy Tribe–Pleasant Point's damages derivative of harm visited upon third party persons or entities not named in this action.

655. By virtue of the foregoing violations of the RICO Act, including 18 U.S.C. § 1962(c), the Defendants are liable to the Passamaquoddy Tribe–Pleasant Point for three times the damages sustained, plus the costs of this suit, including reasonable attorney's fees.

B. OPIOID DIVERSION ENTERPRISE

656. In addition to their participation in the Opioid Marketing Enterprise, the RICO Defendants, including the Manufacturer Defendants, Distributor Defendants, and Retailer Defendants, engaged in a conspiracy to expand the market for opioid drugs—thus inflating their own profits—without regard to legal requirements that Defendants take action to prevent the diversion of drugs to illegal channels.

657. These legal associations and/or associations in fact include, at a minimum, a Manufacturer Defendant, a Distributor Defendant, and a Retailer Defendant (or a smaller and/or local pharmacy not named as a defendant in the instant case). These legal associations and/or associations in fact are, for purposes of the RICO Act, an enterprise (hereinafter, for purpose of this count, an "Enterprise," a "Diversion Enterprise," or collectively, the "Enterprises").

658. Under the present facts, each co-conspirator either (a) agreed to operate or manage the enterprise that did and does feloniously deal in controlled substances, an offense punishable under the laws of the United States, or (b) if a co-conspirator did not agree to operate or manage the enterprise, each co-conspirator knowingly agreed to facilitate others who did and do operate or manage the enterprise of felonious dealing in controlled substances, an offense punishable under the laws of the United States.

659. To illustrate of the concept of an Enterprise, consider the following example. A Manufacturer Defendant manufactures opioids. The Manufacturer Defendant then sells the same opioids to a Distributor Defendant. The Distributor Defendant then distributes, or sells, the same opioids to a Retailer Defendant. Finally, the Retailer Defendant sells the same opioids to the Retailer Defendant's customers who have been provided a prescription for the opioids.

660. To the Manufacturer Defendants, Distributor Defendants, and Retailer Defendants, what the customer does with the opioids once the final sale has been made is irrelevant. He may ingest the opioids for legitimate medical purposes, such as to treat severe acute or chronic pain; he may abuse the opioids personally by ingesting them for recreational purposes or to support a drug habit; or he may give or sell them to a third party abuser who ingests them recreationally or out of habit to support an addiction.

661. Each Diversion Enterprise (which may later include as yet unnamed persons implicated by facts uncovered in the future, including doctors who wrote illegal prescriptions in exchange for cash payments from patients or increase their prescribing practices in exchange for kick-backs from Manufacturer Defendants), and each vertical supply chain therefore constitutes an individual Dealing Enterprise. And any given actor in the Enterprise, whether a Manufacturer Defendant, Distributor Defendant, or Retailer Defendants may belong to one or more Diversion Enterprises.

662. The purpose the Diversion Enterprises, which are schemes organized to maximize the members' profits at all costs, is to manufacture, encourage excessive prescriptions, distribute, and sell as many highly addictive—and often deadly—pills as legally possible. The Enterprises accomplish this by transferring pills down through the supply chain, entity-by-entity, from the manufacturer to the end user (who can be anyone with a prescription that at least appears to be

real). And they do so without regard for federal law requiring them to take affirmative steps to prevent the diversion of drugs onto the illegal marketplace.

663. For over a decade, the RICO Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they produced and sold.

664. The RICO Defendants, however, are not permitted to engage in a limitless expansion through unlawful sales of regulated painkillers. As "registrants," the RICO Defendants operated and continue to operate within the "closed system" created under the Controlled Substances Act, 21 U.S.C. § 821, et seq. (the "CSA"). The CSA restricts the RICO Defendants' ability to manufacture or distribute Schedule II substances like opioids by requiring them to:

a) Register to manufacture or distribute opioids;

b) Maintain effective controls against "diversion" of the controlled substances that they manufacturer or distribute (i.e., the transfer of the drug away from the person for whom it was intended);

c) Design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA; and

d) Make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

665. The closed system created by the CSA, including the establishment of quotas, was specifically intended to reduce or eliminate the diversion of Schedule II substances like opioids from "legitimate channels of trade" to the illicit market.

666. In addition, the CSA imposes strict checks on the size of the market for Schedule II substances such as opioids. The CSA requires the U.S. Attorney General to annually establish

a "production quota" for Schedule II controlled substance—setting the total quantity of "each basic class of controlled substance" that is legally permitted to be produced in the United States. 21 U.S.C. § 826(a). In turn, each manufacturer of Schedule II drugs must apply for an "individual production quota" allowing that specific manufacturer to produce a certain quantity of drugs. *Id.* § 826(b). When setting the aggregate quota for the United States, the Attorney General must consider, among other things, the estimated legitimate demand for such drugs during the coming year. *Id.* § 826(a). When setting the "individual production quota" for manufacturers, the Attorney General must consider, among other things, the manufacturer's current rate of drug disposal and the "trend of the national disposal rate during the preceding calendar year." *Id.* § 826(c).

667. The U.S. Attorney General has delegated the responsibility of setting production quotas to the DEA. 28 C.F.R. § 0.100.

668. Members of the Enterprises systematically violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders, and to notify the DEA of suspicious orders. Consequently, the RICO Defendants allowed hundreds of millions of pills to enter the illicit market, which allowed the RICO Defendants to derive and be unjustly enriched by obscene profits.

669. Defendants' illegal scheme was hatched by an association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants. In particular, each of the RICO Defendants were associated with, and conducted or participated in, the affairs of the RICO enterprise, whose purpose was to engage in the unlawful sales of opioids and deceive the public and federal and state regulators into believing that the RICO Defendants were faithfully fulfilling their statutory obligations.

670. The RICO Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and/or maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits, and market share.

671. The RICO Defendants conducted and participated in the conduct of the Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(A) by the felonious dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), chargeable under State law. The Enterprises are engaged in or affect interstate commerce. The Enterprises are engaged in interstate commerce, or their activities affect interstate commerce, because many of the Enterprise's transactions that occur before opioids arrive in the retail purchaser's possession (a) involve sales between and/or among residents of different states, and/or (b) physical transportation of opioids across state lines.

672. CSA § 102 defines "controlled substance" as a drug or other substance or immediate precursor included in schedule I, II, III, IV, or I of part B of Title II of the Controlled Substances Act.

673. Schedule II controlled substances have a high potential for abuse and have a high potential to lead to physical and/or psychological dependence, despite that such drugs have currently accepted medical uses.

674. Each of the opioids manufactured or sold by the Manufacturer Defendants, Distributor Defendants, and Retailer Defendants is a semi-synthetic opiate or a synthetic opiate, including the branded versions of the Manufacturer Defendants' drugs that include morphine, codeine, oxycodone, hydrocodone, oxymorphone, hydromorphone, methadone, buprenorphine, fentanyl, and other similar drugs that are Schedule II controlled substances or listed chemicals as defined in section 102 of part B of Title II of the CSA.

675. The RICO Defendants committed crimes that are punishable as felonies under the CSA and the laws of Maine.

676. The regulations promulgated under the CSA include a requirement that a person licensed to manufacture, distribute, prescribe, or dispense controlled substances design and operate a system to detect and report "suspicious orders" for controlled substances, as that term is defined in the regulation. *See* 21 C.F.R. §1301.74(b). The provision requiring the reporting of suspicious orders in the federal CSA has been incorporated, via regulation, into Maine law. 02-392 CMR Pt. 5, Ch. 29, §1 (2, 6), §2. A violation of reporting requirements under the CSA is punishable up to 4 years in jail, making it a felony. 21 U.S.C. § 842(a)(4)(A) and (d)(1).

677. Each of the RICO Defendants qualifies as registrants under the CSA and the regulations of the Maine Board of Pharmacy. Their status as registrants under the CSA and Maine law requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances., and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b); 02-392 CMR Pt. 5, Ch. 29, §1 (1-10), §2. Failure to abide by those requirements is a felony.

678. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, had a similar purpose, involved the same or similar participants and methods of commission, and have similar results affecting similar victims, including Plaintiff, the Passamaquoddy Tribe—Pleasant Point. These acts pose a threat of continued racketeering activity and constitute a "pattern of racketeering activity" within the meaning of 18 U.S.C. § 1961(5).

679. Members of each Enterprise participate in the Enterprise's affairs:

a) without regard to their obligations under the CSA, such as the obligation to report suspicious orders;

b) without regard to what effect the Enterprise's operations may have on individuals or the larger community, such as mass overdoses, crime, addiction, and death;

c) without regard to whether the prescriptions presented by purchasers are for legitimate purposes;

d) without regard to whether the size of individual doses or collective volume of doses in individual prescriptions is appropriate, or extremely inappropriate, given the conditions for the opioids prescription;

e) without regard to whether the purchasers did in the past or continue to exhibit drug seeking behavior;

f) without regard to whether the purchasers have a known history of criminal activity inside the Retailer Defendants' store, or on or near their property;

g) without regard to whether an individual customer presents multiple prescriptions from different doctors, who are unaware of each other, during a single month; and

h) without regard to whether prescriptions were written by doctors who have a known history of, or presently continue, engaging in suspicious or downright fraudulent over-prescribing.

680. The Predicate Offenses of the Enterprise are related because they:

a) have the same purpose, results, participants, victims, and/or methods of commission; and/or

b) are otherwise interrelated by distinguishing characteristics, which include, without limitation:

i. commission in the same manner using the same means, such as:

1. intentionally failing to comply with CSA obligations to flag and report orders of controlled substances as suspicious when they meet certain criteria;

2. using aggressive marketing campaigns that encourage overprescribing medications for unapproved uses;

3. claiming that the drugs were far safer, less addictive, and more effective than alternatives, each of which claim is false and misleading; and

4. providing such strong incentives for prescribing that such practices would be better described as bribery or coercion, (and which, in fact, in some cases, resulted in criminal convictions for violations of federal anti-kickback laws).

c) were conducted pursuant to an understanding and agreement, whether explicit or implicit, that each member would participate to facilitate and further the Enterprise's purpose, which was to maximize profits by manufacturing, distributing, and selling as many opioid pills as possible.

681. From at least as early as 1995, and continuing until the time of filing of this complaint, Defendants and others known and unknown did knowingly and intentionally devise and intend to devise an illegal scheme and artifice to increase and maintain profits from unlawful sales of opioids.

682. It was further part of said scheme and artifice that, in order to conceal the inundation of opioids in the stream of commerce, Defendants and their co-conspirators:

a) would and did make representations and statements in national publications;

b) would and did represent that Defendants would comply with their duty to (1) design and operate a system to disclose to the registrant suspicious orders of controlled substances, and (2) disclose the results of such a program to resolve concerns about over-prescription and diversion of opioids; and

c) would and did suppress and destroy records of suspicious orders to hide evidence of over-prescription and diversion.

683. It was further part of said scheme and artifice that Defendants and their co-conspirators would seek to impair, impede, and defeat government authorities' ability to regulate diversion and to impair, impede, and defeat governmental efforts to regulate and control the manufacture and distribution of opioids, and would and did attempt to prevent to the public, Congress, courts and government officials from uncovering those activities.

684. It was further part of said scheme and artifice that Defendants' communications directed toward government officials and courts would be and were designed to preserve and increase the market for prescription opioids while concealing Defendants' role in supporting an illegal market for opioids.

685. Throughout the existence of the Enterprise, the RICO Defendants purposefully failed to comply with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids—all the while espousing to the general public, to Congress, and to federal and state agencies their commitment to preventing diversion of prescription opioids.

686. The felonious dealing described herein were made in furtherance of RICO Defendants' unified scheme to increase and maintain profits from unlawful sales of opioids while thwarting the ability of federal and state regulators to prevent diversion. This unified scheme was

furthered by (1) habitual noncompliance with federal and state law; (2) intensive lobbying of federal and state official to evade further regulation; and (3) increasing and/or maintaining high production quotas for their prescription opioids from which Defendants could profit for as long as possible.

687. The RICO Defendants unlawfully, knowingly and intentionally combined, conspired, confederated, and agreed together with each other, and with others whose names are both known and unknown, to conduct and participate, directly and indirectly, in the overall objective of their unified scheme, and participated in the common course of conduct to fail to prevent the overprescribing and diversion of prescription opioids.

688. Upon information and belief, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders. If any RICO defendant had disclosed and/or withheld suspicious orders, the conspiracy would be endangered.

689. The RICO Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenues while benefitting from, encouraging, indirectly creating, contributing to, and maintaining an illegal secondary market for highly addictive and dangerous drugs. The predicate acts involved the same or similar purposes participants, victims, criminal acts that have the same or similar purposes, results, participants, victims, methods of commission, and are not isolated events.

690. Many of the precise dates of the RICO Defendants' criminal actions are not known and cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the unified scheme alleged herein depended upon secrecy—and,

towards that end, RICO Defendants took deliberate steps to conceal their wrongdoing. However, given the massive scope of the illegal and scheme, RICO Defendants likely committed thousands, if not millions, of predicate acts of racketeering activity.

691. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a unified scheme and unlawful course of conduct constituting a pattern of racketeering activity.

692. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA, and the Code of Federal Regulations, and the regulations of the Maine Board of Pharmacy would harm the Passamaquoddy Tribe–Pleasant Point by allowing the flow of prescriptions opioids from appropriate medical channels into the illicit drug market.

693. The RICO Defendants knowingly and intentionally furnished false information in their reports to the DEA about suspicious orders, and/or omitted material information from reports, records and other document required to be filed with the DEA—including the Manufacturer Defendants' applications for production quotas. Specifically, the RICO Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market, and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

694. The following DEA communications reflect the RICO Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74:

a) On April 24, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against AmerisourceBergen's distribution center in Orlando, Florida ("Orlando Facility"), alleging failure to maintain effective

controls against diversion of controlled substances. On June 22, 2007, AmerisourceBergen entered into a settlement that resulted in the suspension of its DEA registration.

b) On November 28, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against Cardinal Health's distribution center in Auburn, Washington ("Auburn Facility"), for failure to maintain effective controls against diversion of hydrocodone.

c) On December 5, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against Cardinal Health's distribution center in Lakeland, Florida ("Lakeland Facility"), for failure to maintain effective controls against diversion of hydrocodone.

d) On December 7, 2007, the DEA issued an Order to Show Cause and Immediate Suspension Order against Cardinal Health's distribution center in Swedesboro, New Jersey ("Swedesboro Facility"), for failure to maintain effective controls against diversion of hydrocodone.

e) On January 30, 2008, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health's distribution center in Stafford, Texas ("Stafford Facility"), for failure to maintain effective controls against diversion of hydrocodone.

f) On May 2, 2008, McKesson Corporation entered into an Administrative Memorandum of Agreement ("2008 MOA") with the DEA which provided that McKesson would "maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of

suspicious orders required by 21 C.F.R. § 1301.74(b), and follow the procedures established by its Controlled Substance Monitoring Program."

g) On September 30, 2008, Cardinal Health entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with the DEA related to its Auburn Facility, Lakeland Facility, Swedesboro Facility and Stafford Facility. The document also referenced allegations by the DEA that Cardinal failed to maintain effective controls against the diversion of controlled substances at its distribution facilities located in McDonough, Georgia ("McDonough Facility"), Valencia, California ("Valencia Facility") and Denver, Colorado ("Denver Facility").

h) On February 2, 2012, the DEA issued an Order to Show Cause and Immediate Suspension Order against the Cardinal Health's Lakeland Facility for failure to maintain effective controls against diversion of oxycodone.

i) On December 23, 2016, Cardinal Health agreed to pay a $44 million fine to the DEA to resolve the civil penalty portion of the administrative action taken against its Lakeland Facility.

j) On January 5, 2017, McKesson Corporation entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a $150,000,000 civil penalty for violation of the 2008 MOA as well as failure to identify and report suspicious orders at its facilities in Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; LaCrosse, Wisconsin; Lakeland, Florida; Landover, Maryland; La Vista, Nebraska; Livonia, Michigan;

Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California.

695. These actions against the Distributor Defendants confirm that the Distributors knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate, on information and belief, that the Manufacturer Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids. Manufacturer Defendants had a corresponding duty to report these suspicious orders.

696. Given the continuous nature of these offenses—as demonstrated by the number of co-conspirators convicted, the number of predicate offenses committed by the co-conspirators, and the length of time over which they were committed—the pattern of conduct by the co-conspirators presents a significant risk of continued criminal activity and serious, resulting harm.

697. The RICO Defendants' predicate acts of racketeering activity under 18 U.S.C. § 1961(1) in the conduct of the Diversion Enterprise includes Mail Fraud: -The Manufacturer Defendants violated 18 U.S.C. § 1341 by sending and receiving, and by causing to be sent and/or received, materials via U.S. Mail or commercial interstate carriers for the purpose of executing the unlawful scheme to deceptively market, and sell the opioids by means of false pretenses, misrepresentations, promises and omissions.

698. The RICO Defendants' predicate acts of racketeering activity under 18 U.S.C. § 1961(1) in the conduct of the Diversion Enterprise also includes Wire Fraud: The Manufacturer Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, and by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to defraud and obtain money on false pretenses, misrepresentations, promises and omissions.

699. The RICO Defendants further conducted and participated in the conduct of the affairs of the Diversion Enterprise through a pattern of racketeering activity as defined in, and in violation of, 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States. Furthermore, in so doing the acts alleged herein, the members of the Enterprises (the "Co-Conspirators") conspired to violate § 1962(c) of the RICO Act, and they thereby violated § 1962(d) of the RICO Act.

700. Specifically, the Defendants violated 21 U.S.C. § 843(a)(4) by knowingly and intentionally furnishing false information in, and omitting material information from, reports, records, and other documents required to be made, kept, and filed under the relevant subchapter of Title 21 of the United States Code. Such a violation of 21 U.S.C. § 843(a)(4) is punishable by up to four years in jail, making it a felony. 21 U.S.C. § 843(d)(1).

701. The Defendants also violated 18 U.S.C. § 1952, pertaining to interstate and foreign travel or transportation in aid of racketeering enterprises (the "Travel Act), because they used the mail and facilities in interstate commerce (i.e., interstate wires) with the intent to promote, carry on, or facilitate the promotion or carrying on of, "any unlawful activity" within the meaning of 18 U.S.C. § 1952(b), namely, a business enterprise involving narcotics or controlled substances, and thereafter performed or attempted to perform any such unlawful activity, including the foregoing violations of federal law as well as violations of the laws of the State of Maine. Specifically, as set forth hereinabove, the Defendants violated various and numerous provisions of the Maine Pharmacy Act, 32 MSRA § 13701 *et seq*., including the anti-diversion provisions.

702. But for the conduct of the Enterprises' affairs, the Passamaquoddy Tribe–Pleasant Point would not have sustained the damages and injuries set forth herein.

703. By virtue of the foregoing violations of the RICO Act, including 18 U.S.C. § 1962(c), the RICO Defendants are liable to the Passamaquoddy Tribe–Pleasant Point for all their damages and injuries set forth herein and for three times the damages sustained, plus the costs of this suit, including reasonable attorney's fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Passamaquoddy Tribe–Pleasant Point, acting on behalf of itself and on behalf of its members, prays that the Court grant the following relief:

a) Enjoin Defendants from failing to report suspicious orders as required by the federal CSA, as incorporated by the regulations of the Maine Board of Pharmacy, 02-392 CMR Pt. 5, Ch. 29, §1 (2, 6), §2;

b) Awarding Plaintiff, the Passamaquoddy Tribe–Pleasant Point, damages caused by the opioid epidemic, including (1) costs for providing medical care, additional therapeutic and prescription drug purchases, and other treatments for patients suffering from opioid-related addiction or disease, including overdoses and deaths; (2) costs for providing treatment, counseling, and rehabilitation services; (3) costs for providing treatment of infants born with opioid-related medical conditions; (4) costs for providing care for children whose parents suffer from opioid-related disability or incapacitation; and (5) costs associated with law enforcement and public safety relating to the opioid epidemic;

c) Order that Defendants compensate Plaintiff for past and future costs to abate the ongoing public nuisance caused by the opioid epidemic;

d) Order Defendants to fund an "abatement fund" for the purposes of implementing programs necessary to abate the opioid nuisance;

e) Award actual damages, treble damages, injunctive and equitable relief, forfeiture as deemed proper by the Court, and attorney fees and all costs and expenses of suit pursuant to Plaintiffs' racketeering claims;

f) Awarding judgment against the Defendants requiring Defendants to pay punitive damages;

g) The cost of investigation, reasonable attorneys' fees, and all costs and expenses;

h) Pre-judgment and post-judgment interest; and

i) Grant any such further relief as this Court deems appropriate.

Dated: February 28, 2019

Respectfully submitted,

/s/ *John M. Broaddus*

John M. Broaddus (NJ # 01011-2005)
WEITZ & LUXENBERG, P.C.
220 Lake Drive East, Suite 210
Cherry Hill, NJ 08002
Tel: (856) 755-1115
Email: jbroaddus@weitzlux.com

Paul J. Pennock (PP-3315)
Ellen Relkin (ER-9536)
WEITZ & LUXENBERG, P.C.
700 Broadway
New York, NY 10003
Tel: (212) 558-5500
Email: erelkin@weitzlux.com
Email: ppennock@weitzlux.com

Neil T. Leifer (Maine ID# 002425)
NEIL T. LEIFER LLC
16 Kingswood Road
Auburndale, MA 02466
Tel: (617) 429-4892
Email: N.Leifer@ntllaw.com

Kaighn Smith, Jr.(Maine ID# 3301)
Michael-Corey F. Hinton (Maine ID# 6125)
DRUMMOND WOODSUM
84 Marginal Way, Suite 600
Portland, ME 04101-2480
Tel: (207) 772-1941
Email: ksmith@dwmlaw.com
Email: mchinton@dwmlaw.com

Attorneys for Plaintiff